

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 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, 2023

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-41555

**ASP Isotopes Inc.**

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

87-2618235

(I.R.S. Employer  
Identification No.)

1101 Pennsylvania Avenue NW, Suite 300  
Washington, DC

(Address of principal executive offices)

20004

(Zip Code)

Registrant's telephone number, including area code: (202) 756-2245

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.01 per share	ASPI	Nasdaq Stock Market LLC (Nasdaq Capital Market)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
Emerging growth company

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

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

As of November 6, 2023, the registrant had 48,773,276 shares of common stock, \$0.01 par value per share, outstanding.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “should,” “would,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions or references to future periods. The forward-looking statements in this Quarterly Report on Form 10-Q are neither historical facts nor assurances of future performance. We have based these forward-looking statements largely on our current beliefs, expectations and assumptions about the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements relate to the future, they are inherently subject to risks, uncertainties and changes in circumstances, some of which cannot be predicted or quantified and many of which are outside of our control. Therefore, you should not rely on any of these forward-looking statements. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Some of the key factors that could cause actual results to differ from our expectations include:

- our ability to complete the construction of, commission and successfully operate isotope enrichment plants in a cost-effective manner;
- our ability to meet, and to continue to meet, applicable regulatory requirements for the use of the isotopes we may produce using the ASP technology or the Quantum Enrichment Process;
- our ability to obtain regulatory approvals for the production and distribution of isotopes;
- our ability to comply on an ongoing basis with the numerous regulatory requirements applicable to the ASP technology, the Quantum Enrichment Process and our enrichment facilities in South Africa;
- the introduction, market acceptance and success of Mo-100 that we may produce using ASP technology as an alternative and potentially more convenient production route for Tc-99m;
- the success or profitability of our future offtake arrangements with respect to various isotopes that we may produce using ASP technology or the Quantum Enrichment Process;
- a failure of demand for various isotopes that we may produce using ASP technology or the Quantum Enrichment Process;
- our future capital requirements and sources and uses of cash;
- our ability to obtain funding for our operations and future growth;
- the extensive costs, time and uncertainty associated with new technology development;
- developments and projections relating to our competitors and industry;
- the ability to recognize the anticipated benefits of the acquisition of assets of Molybdos (Pty) Limited in the “business rescue” auction and the ASP technology for the production of isotopes;
- problems with the performance of the ASP technology or the Quantum Enrichment Process in the enrichment of isotopes;
- our dependence on a limited number of third party suppliers for certain components;
- our inability to adapt to changing technology and diagnostic landscape, such as the emergence of new diagnostic scanners or tracers;
- our expected dependence on a limited number of key customers for isotopes that we may produce using ASP technology or the Quantum Enrichment Process;
- our inability to protect our intellectual property and the risk of claims that we have infringed on the intellectual property of others;
- our inability to compete effectively;
- risks associated with the current economic environment;
- risks associated with our international operations;
- geopolitical risk and changes in applicable laws or regulations;
- our inability to adequately protect our technology infrastructure;
- our inability to hire or retain skilled employees and the loss of any of our key personnel;
- operational risk;
- we are subject to credit counterparty risks;
- costs and other risks associated with becoming a reporting company and becoming subject to the Sarbanes-Oxley Act;
- our inability to implement and maintain effective internal controls; and
- other factors that are described in “Risk Factors,” beginning on page 37.

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These statements relate to future events or to our future financial performance and 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 these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Part II, Item 1A - "Risk Factors" below and for the reasons described elsewhere in this Quarterly Report on Form 10-Q. Any forward-looking statement in this Quarterly Report on Form 10-Q reflects our current view with respect to future events and is subject to these and other risks, uncertainties, and assumptions relating to our operations, results of operations, industry, and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections, and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by third parties, industry, medical and general publications, government data, and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Except where the context otherwise requires, in this Quarterly Report on Form 10-Q, "we," "us," "our," "ASP Isotopes," and the "Company" refer to ASP Isotopes Inc. and, where appropriate, its consolidated subsidiaries.

**Trademarks**

All trademarks, service marks, and trade names included in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I-FINANCIAL INFORMATION

Item 1. Financial Statements.

ASP Isotopes Inc.  
Condensed Consolidated Balance Sheets  
(unaudited)

	September 30, 2023	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash	\$ 2,286,805	\$ 2,389,140
Prepaid expenses and other current assets	441,820	913,005
Total current assets	2,728,625	3,302,145
Property and equipment, net	8,346,920	8,200,595
Operating lease right-of-use asset, net	622,183	853,889
Other noncurrent assets	173,664	139,636
<b>Total assets</b>	<b>\$ 11,871,392</b>	<b>\$ 12,496,265</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 401,956	\$ 1,354,903
Accrued expenses	1,092,328	361,246
Notes payable	33,854	33,854
Operating lease liability - current	48,975	45,903
Deferred revenue	882,000	-
Share liability	142,500	140,455
Total current liabilities	2,601,613	1,936,361
Operating lease liability - noncurrent	630,292	742,443
Total liabilities	3,231,905	2,678,804
<b>Commitments and contingencies (Note 7)</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized, no shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common stock, \$0.01 par value; 500,000,000 shares authorized, 38,348,184 and 35,907,127 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	383,482	359,071
Additional paid-in capital	29,219,118	16,756,426
Accumulated deficit	(19,676,973)	(7,553,066)
Accumulated other comprehensive (loss) income	(1,286,140)	255,030
<b>Total stockholders' equity</b>	<b>8,639,487</b>	<b>9,817,461</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 11,871,392</b>	<b>\$ 12,496,265</b>

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

**ASP Isotopes Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
<b>Operating expenses:</b>				
Research and development	\$ 239,199	\$ 745,461	\$ 699,413	\$ 1,191,901
General and administrative	3,707,311	1,208,319	11,319,465	2,448,091
Total operating expenses	<u>3,946,510</u>	<u>1,953,780</u>	<u>12,018,878</u>	<u>3,639,992</u>
<b>Loss from operations</b>	<b>(3,946,510)</b>	<b>(1,953,780)</b>	<b>(12,018,878)</b>	<b>(3,639,992)</b>
<b>Other income (expense):</b>				
Foreign exchange transaction loss	-	-	(935)	-
Change in fair value of share liability	(279,425)	(2,903)	(109,040)	(2,093)
Interest income	3,452	453	4,946	1,907
Total other expense, net	<u>(275,973)</u>	<u>(2,450)</u>	<u>(105,029)</u>	<u>(996)</u>
<b>Net loss</b>	<b>\$ (4,222,483)</b>	<b>\$ (1,956,230)</b>	<b>\$ (12,123,907)</b>	<b>\$ (3,640,988)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.14)</b>	<b>\$ (0.06)</b>	<b>\$ (0.40)</b>	<b>\$ (0.13)</b>
<b>Weighted average shares of common stock outstanding, basic and diluted</b>	<b><u>31,147,749</u></b>	<b><u>30,107,127</u></b>	<b><u>29,954,321</u></b>	<b><u>28,642,533</u></b>
<b>Other comprehensive loss:</b>				
Net loss	\$ (4,222,483)	\$ (1,956,230)	\$ (12,123,907)	\$ (3,640,988)
Foreign currency translation	(64,644)	150,501	(1,541,170)	275,772
<b>Total comprehensive loss</b>	<b><u>\$ (4,287,127)</u></b>	<b><u>\$ (1,805,729)</u></b>	<b><u>\$ (13,665,077)</u></b>	<b><u>\$ (3,365,216)</u></b>

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

**ASP Isotopes Inc.**  
**Condensed Consolidated Statements of Changes in Stockholders' Equity**  
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of December 31, 2022</b>	<b>35,907,127</b>	<b>\$ 359,071</b>	<b>\$ 16,756,426</b>	<b>\$ 255,030</b>	<b>\$ (7,553,066)</b>	<b>\$ 9,817,461</b>
Issuance of common stock and warrants, net of issuance costs of \$506,390	3,164,557	31,646	4,461,964	-	-	4,493,610
Cancellation of common stock received in exchange for issuance of preferred stock in subsidiary	(3,000,000)	(30,000)	30,000	-	-	-
Issuance of common stock in lieu of commissions	57,250	573	74,997	-	-	75,570
Issuance of restricted common stock	1,256,750	12,567	(12,567)	-	-	-
Stock-based compensation	-	-	2,144,099	-	-	2,144,099
Foreign currency translation	-	-	-	(1,003,853)	-	(1,003,853)
Net loss	-	-	-	-	(3,615,078)	(3,615,078)
<b>Balance as of March 31, 2023</b>	<b>37,385,684</b>	<b>\$ 373,857</b>	<b>\$ 23,454,919</b>	<b>\$ (748,823)</b>	<b>\$ (11,168,144)</b>	<b>\$ 11,911,809</b>
Settlement of liabilities with related party	-	-	626,223	-	-	626,223
Stock-based compensation	-	-	2,374,686	-	-	2,374,686
Foreign currency translation	-	-	-	(472,673)	-	(472,673)
Net loss	-	-	-	-	(4,286,346)	(4,286,346)
<b>Balance as of June 30, 2023</b>	<b>37,385,684</b>	<b>\$ 373,857</b>	<b>\$ 26,455,828</b>	<b>\$ (1,221,496)</b>	<b>\$ (15,454,490)</b>	<b>\$ 10,153,699</b>
Issuance of restricted common stock	500,000	5,000	(5,000)	-	-	-
Settlement of liabilities with consultants	462,500	4,625	696,500	-	-	701,125
Stock-based compensation	-	-	2,071,790	-	-	2,071,790
Foreign currency translation	-	-	-	(64,644)	-	(64,644)
Net loss	-	-	-	-	(4,222,483)	(4,222,483)
<b>Balance as of September 30, 2023</b>	<b>38,348,184</b>	<b>\$ 383,482</b>	<b>\$ 29,219,118</b>	<b>\$ (1,286,140)</b>	<b>\$ (19,676,973)</b>	<b>\$ 8,639,487</b>
<b>Balance as of December 31, 2021</b>	<b>20,652,500</b>	<b>\$ 206,525</b>	<b>\$ 8,380,343</b>	<b>\$ 18,723</b>	<b>\$ (2,607,927)</b>	<b>\$ 5,997,664</b>
Issuance of common stock and warrants, net of issuance costs of \$285,024	1,187,605	11,876	2,078,310	-	-	2,090,186
Issuance of common stock upon exercise of warrants	7,194,847	71,948	(71,948)	-	-	-
Stock-based compensation	-	-	20,803	-	-	20,803
Foreign currency translation	-	-	-	(229,257)	-	(229,257)
Net loss	-	-	-	-	(857,588)	(857,588)
<b>Balance as of March 31, 2022</b>	<b>29,034,952</b>	<b>\$ 290,349</b>	<b>\$ 10,407,508</b>	<b>\$ (210,534)</b>	<b>\$ (3,465,515)</b>	<b>\$ 7,021,808</b>
Issuance of common stock, net of issuance costs of \$95,723	372,175	3,722	644,904	-	-	648,626
Stock-based compensation	-	-	210,745	-	-	210,745
Foreign currency translation	-	-	-	354,528	-	354,528
Net loss	-	-	-	-	(827,170)	(827,170)
<b>Balance as of June 30, 2022</b>	<b>29,407,127</b>	<b>\$ 294,071</b>	<b>\$ 11,263,157</b>	<b>\$ 143,994</b>	<b>\$ (4,292,685)</b>	<b>\$ 7,408,537</b>
Issuance of restricted common shares	700,000	7,000	(7,000)	-	-	-
Stock-based compensation expense	-	-	715,410	-	-	715,410
Foreign currency translation	-	-	-	150,501	-	150,501
Net loss	-	-	-	-	(1,956,230)	(1,956,230)
<b>Balance as of September 30, 2022</b>	<b>30,107,127</b>	<b>\$ 301,071</b>	<b>\$ 11,971,567</b>	<b>\$ 294,495</b>	<b>\$ (6,248,915)</b>	<b>\$ 6,318,218</b>

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

**ASP Isotopes Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
**(unaudited)**

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from Operating activities</b>		
Net loss	\$ (12,123,907)	\$ (3,640,988)
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>		
Depreciation	969	-
Stock-based compensation	6,590,576	946,958
Fair value of common stock to consultants	669,700	-
Change in fair value of share liability	109,040	2,903
Change in right-of-use lease asset	49,173	51,624
<b>Changes in operating assets and liabilities:</b>		
Deferred offering costs	-	(547,373)
Prepaid expenses and other current assets	132,677	(337,612)
Other noncurrent assets	(48,812)	(131,408)
Accounts payable	(298,663)	763,695
Accrued expenses	712,368	935,039
Deferred revenue	882,000	-
Lease liability	(30,292)	(120,697)
<b>Net cash used in operating activities</b>	<b>(3,355,171)</b>	<b>(2,077,859)</b>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(1,190,157)	(3,570,632)
<b>Net cash used in investing activities</b>	<b>(1,190,157)</b>	<b>(3,570,632)</b>
<b>Cash flows from financing Activities</b>		
Proceeds from issuance of common stock	5,000,000	3,119,560
Common stock issuance costs	(506,390)	(255,965)
Repayment of notes payable	-	(13,046)
<b>Net cash provided by financing activities</b>	<b>4,493,610</b>	<b>2,850,549</b>
<b>Net change in cash</b>	<b>(51,718)</b>	<b>(2,797,942)</b>
Effect of exchange rate changes on cash	(50,617)	275,786
Cash - beginning of period	2,389,140	2,953,721
<b>Cash - end of period</b>	<b>\$ 2,286,805</b>	<b>\$ 431,565</b>
<b>Supplemental disclosures of non-cash investing and financing activities:</b>		
Settlement of liabilities with related party	\$ 626,223	\$ -
Share liability for non-cash issuance costs	\$ -	\$ 124,782
Purchase of property and equipment included in accounts payable	\$ -	\$ 332,879
Settlement of share liability	\$ 776,695	\$ -

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



**ASP Isotopes Inc.**  
**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Organization**

***Description of Business***

ASP Isotopes Inc. was incorporated in the state of Delaware on September 13, 2021, and has its principal operations in Washington, DC. ASP Isotopes Inc.'s subsidiary, ASP Isotopes Holdings Limited ("ASP Guernsey"), has its principal operations in Guernsey. ASP Guernsey's subsidiary, ASP Isotopes Holdings South Africa Proprietary Limited ("ASP South Africa"), has its principal operations in South Africa. Enlightened Isotopes (Pty) Ltd ("Enlightened Isotopes"), an 80% owned subsidiary of ASP South Africa, was formed in March 2023. ASP Isotopes UK Ltd, a wholly-owned subsidiary of ASP Guernsey, was incorporated in July 2022. Enriched Energy, LLC, a wholly-owned subsidiary of the Company, was incorporated in January 2022. Quantum Leap Energy LLC, a wholly-owned subsidiary of the Company, was formed in the state of Delaware in September 2023. Quantum Leap Energy Ltd, a company registered in England & Wales and a wholly-owned subsidiary of Quantum Leap Energy LLC, was incorporated in September 2023. ASP Isotopes Inc. and its subsidiaries are collectively referred to as "the Company" throughout these consolidated statements.

The Company is a pre-commercial stage advanced materials company dedicated to the development of technology and processes that, if successful, will allow for the enrichment of natural isotopes into higher concentration products, which could be used in several industries. The Company's proprietary technology, the Aerodynamic Separation Process ("ASP technology"), originally developed by Klydon Proprietary Ltd ("Klydon"), is designed to enable the production of isotopes used in several industries. The Company's initial focus is on the production and commercialization of enriched Carbon-14 ("C-14"), Molybdenum-100 ("Mo-100") and Silicon-28 ("Si-28"). The Company has commissioned its first isotope enrichment plant for the enrichment of C-14 located in Pretoria, South Africa, and anticipates completion and commissioning of its second multi-isotope enrichment plant in Pretoria, South Africa during the first half of 2024. In addition, the Company has started planning additional isotope enrichment plants. The Company believes the C-14 it may develop using the ASP technology could be used in the development of new pharmaceuticals and agrochemicals. The Company believes that the Mo-100 it may produce using the ASP technology could have significant potential advantages for use in the preparation of nuclear imaging agents by radiopharmacies and others in the medical industry. The Company believes the Si-28 it may produce using the ASP technology may be used to develop advanced semiconductors and in quantum computing.

The Company is also developing quantum enrichment technology to produce enriched Ytterbium-176, Nickel-64, Lithium 6, Lithium7 and Uranium-235 ("U-235"). Quantum enrichment is an advanced isotope enrichment technique that is currently in development that uses lasers. The Company believes that the U-235 it may develop using quantum enrichment could be commercialized as a nuclear fuel component for use in the new generation of HALEU-fueled small modular reactors that are now under development for commercial and government uses.

***Liquidity and Going Concern Uncertainty***

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes the Company is a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from any uncertainty related to the Company's ability to continue as a going concern. Such adjustments could be material. The Company has experienced net losses and negative cash flows from operating activities since its inception. The Company incurred net losses of \$12,123,907 and \$3,640,988 for the nine months ended September 30, 2023 and 2022, respectively. The Company anticipates it will need to continue to raise capital through additional equity and/or debt financings and/or collaborative development agreements to fund its operations.

The Company currently expects that its cash of \$2,286,805 as of September 30, 2023 and \$9,129,461 of aggregate proceeds received in October 2023 from the issuance of 9,952,510 shares of common stock at between \$0.92 and \$0.96 per share, will not be sufficient to fund its operating expenses and capital requirements for more than 12 months from the date the financial statements are issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Additional funding will be necessary to complete construction of the first enrichment facility and begin operations, and although the Company has plans to seek additional funding, these plans are not currently probable.

There can be no assurance that the Company will achieve or sustain positive cash flows from operations or profitability. The Company is in the process of seeking additional debt and equity financing. However, such funding may not be available on a timely basis on terms acceptable to the Company, or at all. If the Company is unable to raise additional capital when required or on acceptable terms, the Company may be required to further scale back or discontinue the advancement of product candidates, further reduce headcount, reorganize, merge with another entity, or cease operations.

## **2. Basis of Presentation and Summary of Significant Accounting Policies**

### ***Unaudited Financial Information***

The Company's unaudited condensed consolidated financial statements included herein have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. In the Company's opinion, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and related notes for the year ended December 31, 2022.

### ***Basis of Presentation and Use of Estimates***

The Company's condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of the Company's condensed consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and disclosure in the Company's condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to the valuation of equity instruments and estimating our accrued research and development expenses. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

### ***Principles of consolidation***

The Company's condensed consolidated financial statements include the accounts of ASP Isotopes Inc. and its wholly-owned subsidiaries and, beginning in 2023, the 80% owned Enlightened Isotopes. All intercompany balances and transactions have been eliminated in consolidation. For the three and nine months ended September 30, 2023 and 2022, there was no other corporate activity for Enlightened Isotopes other than its formation and therefore there was no non-controlling interest to report on the consolidated balance sheet and no net loss attributable to non-controlling interest on the consolidated statement of operations and comprehensive loss to report. See Note 10.

### ***Currency and currency translation***

The condensed consolidated financial statements are presented in U.S. dollars, the Company's reporting currency. The functional currency of ASP Isotopes Inc. and ASP Guernsey is the U.S. dollar. The functional currency of the Company's subsidiary ASP South Africa is the South African Rand. Adjustments that arise from exchange rate changes on transactions of each group entity denominated in a currency other than the functional currency are included in other income and expense in the consolidated statements of operations. Assets and liabilities of ASP South Africa are recorded in their South African Rand functional currency and translated into the U.S. dollar reporting currency of the Company at the exchange rate on the balance sheet date. Revenue, when recorded, and expenses of ASP South Africa are recorded in their South African Rand functional currency and translated into the U.S. dollar reporting currency of the Company at the average exchange rate prevailing during the reporting period. Resulting translation adjustments are recorded separately in stockholders' equity as a component of accumulated other comprehensive income (loss). The effect of exchange rate changes on intercompany transactions of a long term and permanent nature are credited or charged directly to a separate component of stockholder's equity.

**Concentration of Credit Risk and other Risks**

Cash balances are maintained at U.S. financial institutions and may exceed the Federal Deposit Insurance Corporation (“FDIC”) insurance limit of \$250,000 per depositor, per insured bank for each account ownership category. Although the Company currently believes that the financial institutions with whom it does business, will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so. The Company has not experienced any credit losses associated with its balances in such accounts for the three and nine months ended September 30, 2023 and 2022.

Our foreign subsidiaries held cash of approximately \$187,515 and \$38,000 as of September 30, 2023 and December 31, 2022, respectively, which is included in cash on the consolidated balance sheets. Our strategic plan does not require the repatriation of foreign cash in order to fund our operations in the U.S., and it is our current intention to indefinitely reinvest our foreign cash outside of the U.S. If we were to repatriate foreign cash to the U.S., we would be required to accrue and pay U.S. taxes in accordance with applicable U.S. tax rules and regulations as a result of the repatriation.

**Cash**

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents are stated at fair value and may include money market funds, U.S. Treasury and U.S. government-sponsored agency securities, corporate debt, commercial paper and certificates of deposit. The Company had no cash equivalents as of September 30, 2023 and December 31, 2022.

**Segment Information**

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The financial information is regularly reviewed by the chief operating decision maker (“CODM”) in deciding how to allocate resources. The Company’s CODM is its chief executive officer.

**Fair Value of Financial Instruments**

Accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company’s share liability (Note 10) is now measured as a Level 1 fair value on a recurring basis and was \$142,500 as of September 30, 2023. There were no transfers among Level 1, Level 2 or Level 3 categories in the nine months ended September 30, 2023. There was a transfer of the share liability from Level 3 to Level 1 as a result of our IPO in the fourth quarter of 2022 as further discussed in Note 10. The following table provides a reconciliation of the Company’s liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3 then Level 1 following the IPO in the fourth quarter of 2022):

	<b>Share Liability</b>
Balance, December 31, 2021	116,200
Fair value of additional common stock issuable	174,782
Fair value adjustment	<u>(150,527)</u>
Balance, December 31, 2022	140,455
Settlement of share liability	(776,695)
Fair value of additional common stock issuable	669,700
Fair value adjustment	109,040
Balance, September 30, 2023	<u>\$ 142,500</u>

The carrying amounts of accounts payable, accrued expenses and notes payable are considered to be representative of their respective fair values because of the short-term nature of those instruments.

#### ***Property and Equipment***

Property and equipment include costs of assets constructed, purchased or leased under a finance lease, related delivery and installation costs and interest incurred on significant capital projects during their construction periods. Expenditures for renewals and betterments also are capitalized, but expenditures for normal repairs and maintenance are expensed as incurred. Costs associated with yearly planned major maintenance are generally deferred and amortized over 12 months or until the same major maintenance activities must be repeated, whichever is shorter. The cost and accumulated depreciation applicable to assets retired or sold are removed from the respective accounts, and gains or losses thereon are included in the statement of operations and comprehensive loss.

We assign the useful lives of our property and equipment based upon our internal engineering estimates, which are reviewed periodically. The estimated useful lives of our property and equipment range from 3 to 5 years, or the shorter of the useful life or remaining life of the lease for leasehold improvements. Depreciation is recorded using the straight-line method.

Construction in progress (Note 3) is carried at cost and consists of specifically identifiable direct and indirect development and construction costs. While under construction, costs of the property are included in construction in progress until the property is placed in service, at which time costs are transferred to the appropriate property and equipment account, including, but not limited to, leasehold improvements or other such accounts.

#### ***Leases***

Leases are accounted for in accordance with ASC 842, which establishes a right-of-use model ("ROU") that requires a lessee to recognize an ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement as well as the reduction of the right-of-use asset. The new standard provides a number of optional practical expedients in transition. The Company has elected to apply (i) the practical expedient, which allows us to not separate lease and non-lease components, for new leases and (ii) the short-term lease exemption for all leases with an original term of less than 12 months, for purposes of applying the recognition and measurements requirements in the new standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company will utilize the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

The Company has elected to combine lease and non-lease components as a single component. Operating leases are recognized on the balance sheet as ROU lease assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances, while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

#### ***Impairment of Long-lived Assets***

Long-lived assets consist primarily of property and equipment. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset is not recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the asset exceeds the fair value of the assets. Fair value would be assessed using a discounted cash flows or other appropriate measures of fair value. The Company did not recognize any impairment losses for the three and nine months ended September 30, 2023 or 2022.

#### ***Research and Development Costs***

Research and development costs consist primarily of fees paid to consultants and facilities costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. All research and development costs are expensed as incurred.

#### ***General and Administrative Costs***

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, business development, legal, human resources and support functions. Other general and administrative expenses include professional fees for auditing, tax, consulting and patent-related services, rent and utilities and insurance.

#### ***Stock-based Compensation***

Stock-based compensation expense represents the cost of the grant date fair value of employee stock awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company estimates the fair value of each stock-based award on the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model incorporates various assumptions, such as the value of the underlying common stock, the risk-free interest rate, expected volatility, expected dividend yield, and expected life of the options. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur.

The Company also awards restricted stock to employees and directors. Restricted stock is generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. The Company expenses the cost of the restricted stock, which is determined to be the fair market value of the shares of common stock underlying the restricted stock at the date of grant, ratably over the period during which the vesting restrictions lapse.

Equity-based compensation expense is classified in the statement of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

Prior to the Company's IPO in November 2022, there was no public market for the Company's common stock. The fair value of the shares of common stock underlying the Company's share-based awards was estimated on each grant date by the Company's board of directors based on then current facts and circumstances. To determine the fair value of the Company's common stock underlying option grants, the board of directors considered, among other things, input from management and recent third-party financings consummated by the Company.

### **Income Taxes**

Deferred income tax assets and liabilities arise from temporary differences associated with differences between the financial statements and tax basis of assets and liabilities, as measured by the enacted tax rates, which are expected to be in effect when these differences reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company has generated net losses since inception and accordingly has not recorded a provision for income taxes.

The Company follows the provisions of ASC 740-10, *Uncertainty in Income Taxes*, or ASC 740-10. The Company has not recognized a liability for any uncertain tax positions. A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there is no unrecognized benefit since the date of adoption. The Company has not recognized interest expense or penalties as a result of the implementation of ASC 740-10. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits and penalties in income tax expense.

The Company has identified the United States, Washington, D.C., South Africa and Guernsey as its major tax jurisdictions. Refer to Note 12 for further details.

### **Comprehensive Loss**

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss is comprised of net loss and the effect of currency translation adjustments.

### **Revenue**

Under ASC 606, *Revenue from Contract with Customers*, an entity recognizes revenue when or as its customer obtains control of distinct promised goods, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we will perform the following five steps: (i) identification of the promised goods in the contract; (ii) determination of whether the promised goods are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We will only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods it transfers to the customer.

Our customer arrangements will primarily consist of performance obligations for promised goods in a contract to transfer a distinct good to the customer and are considered distinct when (i) the customer can benefit from the good on its own or together with other readily available resources and (ii) the promised good is separately identifiable from other promises in the contract. In assessing whether promised goods are distinct, we will consider factors such as whether the goods are integral or dependent of other goods in the contract.

We will estimate the transaction price based on the amount expected to be received for transferring the promised goods in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, we will evaluate the amount of potential payments and the likelihood that the payments will be received. We will utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration which is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

We will allocate the transaction price based on the estimated stand-alone selling price of each of the performance obligations. We must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in a contract with a customer. Any variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amount we would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods. We will evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

To the extent we receive payments, including non-refundable payments, in excess of the recognized revenue, such excess is recorded as deferred revenue until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

### **Recently Issued Accounting Pronouncements**

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). ASU 2016-13 requires measurements and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments- Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments. The ASU 2016-13 guidance became effective as of January 1, 2023, and must be adopted using a modified retrospective approach, with certain exceptions. The adoption of ASU No. 2016-13 as of January 1, 2023 did not have a material impact on the financial statements.

The Company has reviewed recently issued accounting pronouncements and plans to adopt those that are applicable to it. The Company does not expect the adoption of any recently issued pronouncements to have a material impact on its results of operations or financial position.

### **3. Property and Equipment**

Property and equipment consist of the following:

	<b>September 30, 2023</b>	<b>December 31, 2022</b>
Construction in progress	\$ 8,335,569	\$ 8,200,595
Office equipment	12,308	-
Total cost	8,347,877	8,200,595
Accumulated depreciation	(957)	-
Net book value	<u>\$ 8,346,920</u>	<u>\$ 8,200,595</u>

The Company is currently building out and qualifying the plant and office space in South Africa. All costs incurred are considered construction in progress because the work is not complete as of September 30, 2023 and December 31, 2022.

Depreciation expense for the three and nine months ended September 30, 2023 was \$802 and \$969. There was no depreciation expense for the three and nine months ended September 30, 2022.

### **4. Accrued Expenses**

Accrued expenses consisted of accrued professional fees and employee compensation costs as of September 30, 2023 and December 31, 2022.

### **5. Notes Payable**

During 2021, the Company executed promissory notes payable with two individuals with an aggregate principal balance of approximately \$6,900 (35,000 GBP). The notes were due after a period of two months, followed by mutually agreed upon monthly extensions, and do not bear interest. Subsequent to the issuance of the notes payable, one of the individuals became an officer of the Company.

In March 2022, one of the promissory notes totaling \$13,046 (10,000 GBP) was repaid in full. As of September 30, 2023 and December 31, 2022, the total promissory notes payable balance was \$33,854 and have been automatically extended on a monthly basis.

## 6. Deferred Revenues

In June 2023, the Company entered into a Supply Agreement with a customer for the delivery of Molybdenum-100 and molybdenum-98 beginning in 2024. In conjunction with the Supply Agreement, the company received \$882,000 in September 2023, as an advance towards future revenue. The Company has recorded \$82,000 as deferred revenue on the balance sheet as of September 30, 2023. The Company did not recognize any deferred revenue as of December 31, 2022 or January 1, 2022.

## 7. Commitments and Contingencies

### *Klydon Proprietary Limited*

In November 2021, the Company entered into an agreement with Klydon Proprietary Limited (“Klydon”) to design and build a plant to enrich Molybdenum in South Africa. The initial phase of the project includes the building of a plant that can support the production of at least 5kgs of Mo-100, and is expected to be completed in the first quarter of 2024. The contracted cost for this phase is \$6,800,000. The second phase of the project includes the production to be increased to 20kgs of Mo-100 with an additional cost of \$6,000,000. The Company can modify the contract scope and overall costs and the contract can be cancelled by either party. As of September 30, 2023 and December 31, 2022, approximately \$7,233,000 has been paid under this contract and recorded as construction in progress within property and equipment.

Klydon performed a portion of the services required under the Turnkey Contract; however, services were incomplete and many of the services were not completed within the time frame required. As a result, Klydon and ASP South Africa entered into an Acknowledgement of Debt Agreement dated November 30, 2022, whereby Klydon (i) agreed to pledge its assets (the “Pledged Assets”) to ASP South Africa to secure its performance of the Turnkey Contract by December 31, 2022, and (ii) acknowledged that ASP South Africa would suffer damages in the amount of \$6,050,000 (“Damage Amount”) should it fail to perform. Under the Acknowledgement of Debt Agreement, the Pledged Assets would serve as collateral for Klydon’s obligation to pay the Damage Amount should Klydon fail to perform. In connection therewith, also on November 30, 2022, ASP South Africa and Klydon entered into a Deed of Security Agreement whereby, if Klydon failed to complete its obligations under the Turnkey Contract by December 31, 2022, all of Klydon’s rights of any nature to and interests of any nature in the Pledged Assets would be transferred to ASP South Africa. Klydon failed to complete its obligations under the Turnkey Contract by December 31, 2022, however, the Company did not perfect its interests in the assets until April 4, 2023. The Company did not believe that the amounts owed by Klydon were realizable, nor did the Company know the timing of any recovery payments. Therefore, a loss recovery receivable was not recorded at any time prior to April 4, 2023.

On April 4, 2023, the Company perfected its interest under the Acknowledgement of Debt Agreement, pursuant to which the Company acquired certain intellectual property from Klydon (“Klydon Settlement”). In addition, the Company acquired Klydon’s interest in four entities which are inactive and in the process of being dissolved. The Company has concluded that the Klydon Settlement is accounted for under ASC 805, Business Combinations as an asset acquisition since the assets acquired were concentrated in a single identifiable asset from a related party. In conjunction with the Klydon Settlement, the Company recorded an increase to additional paid-in capital for the settlement of all liabilities owed to Klydon at the time of settlement totaling \$626,223.

Two individuals who are officers and board members of Klydon, one who is now an officer of ASP Isotopes Inc. and the other who is now a scientific advisor of ASP Isotopes Inc., received warrants to purchase common stock of the Company and therefore are considered related parties. See Notes 9 and 10.



### **Share Purchase Agreement relating to PET Labs**

On October 30, 2023, the Company entered into a Share Purchase Agreement with Nucleonics Imaging Proprietary Limited, a company incorporated in the Republic of South Africa (the “Seller”), relating to the purchase and sale of ordinary shares in the issued share capital of Pet Labs Pharmaceuticals Proprietary Limited, a company incorporated in the Republic of South Africa (“PET Labs”). PET Labs is a South African radiopharmaceutical operations company, dedicated to nuclear medicine and the science of radiopharmaceutical production.

Under the Purchase Agreement, the Company has agreed to purchase from the Seller 51 ordinary shares in the issued share capital of PET Labs (the “Initial Sale Shares”) (representing 51% of the issued share capital of PET Labs) and has an option to purchase from the Seller the remaining 49 ordinary shares in the issued share capital of PET Labs (the “Option Shares”) (representing the remaining 49% of the issued share capital of PET Labs). The Company agreed to pay to the Seller an aggregate of \$2,000,000 for the Initial Sale Shares, of which aggregate amount \$500,000 was payable on the completion of the sale of the Initial Sale Shares and \$1,500,000 is payable on demand after one calendar year from the agreement date. If the Company exercises its option to purchase the Option Shares (which option is exercisable from the agreement date until January 31, 2027, provided that the Initial Sale Shares have been paid for in full), the Company has agreed to pay \$2,200,000 for the Option Shares.

### **Contingencies**

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues liabilities for such matters when future expenditures are probable and such expenditures can be reasonably estimated.

On October 25, 2022, the Company received a letter from a law firm acting on behalf of Norsk Medisinsk Syklotronsenter AS (“NMS”), asserting, among other things, that the grant of a license to the ASP technology to the Company by Klydon violates a pre-existing exclusive sub-license to the ASP technology granted to Radfarma. The asserted claims, arbitration and/or litigation could include claims against the Company, the Company’s former licensor (Klydon), or Klydon’s present or former sub-licensors alleging infringement of intellectual property rights with respect to the ASP technology on which our company relies. In November 2023, the Company entered into a mutual release with NMS, Radfarma, and certain board members and shareholders of Radfarma related to the claims asserted in the NMS letter and other matters, without any payment or license of any rights by any party to the release.

### **8. Lease**

The Company accounts for leases in accordance with ASC 842 (Note 2). The Company is party to two leases in South Africa. One is an operating lease in Pretoria, South Africa for office and laboratory space. The other is a short term operating lease in Pretoria, South Africa that includes office and laboratory space.

The operating lease commenced in October 2021 with the initial term set to expire in December 2030. The Company has applied the guidance in ASC 842 and has determined that it should be classified as an operating lease. The Company’s incremental borrowing rate is approximately 7.5% based on the lease term of the applicable lease. Consequently, a ROU lease asset of approximately \$952,521 with a corresponding lease liability of approximately \$952,521 based on the present value of the minimum rental payments of such lease was recorded at the inception of the lease. In the consolidated balance sheet as of September 30, 2023, the Company has a ROU asset balance of \$622,183 and a current and non-current lease liability of \$48,975 and \$630,292, respectively, relating to the ROU lease asset. The balance of both the ROU lease asset and the lease liabilities primarily consists of future payments under the Company’s lease in South Africa.

The short term operating lease commenced in April 2023 with the initial term set to expire in April 2024. The Company has applied the short-term lease practical expedient from the guidance in ASC 842 and will expense the monthly rent as incurred.

Quantitative information regarding the Company’s operating lease for the three and nine months ended September 30, 2023 and 2022 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
<b>Lease Cost</b>				
Operating lease cost	\$ 29,654	\$ 32,452	\$ 88,962	\$ 97,357
	<b>Other Information</b>			
Operating cash flows paid for amounts included in the measurement of lease liabilities	\$ 24,559	\$ 20,585	\$ 70,080	\$ 71,343
Remaining lease term (years)	7.25	8.25	7.25	8.25
Discount rate	7.5%	7.5%	7.5%	7.5%

Future lease payments under noncancelable leases are as follows as of September 30, 2023:

	<b>Operating Leases</b>
<b>Future Lease Payments</b>	
2023 (remaining three months)	\$ 24,125
2024	100,119
2025	107,628
2026	115,700
2027	124,377
Thereafter	431,952
Total lease payments	\$ 903,901
Less: imputed interest	(224,634)
Total lease liabilities	\$ 679,267
Less current portion	(48,975)
Lease liability - noncurrent	\$ 630,292

Lease expense from the short term operating lease for the three and nine months ended September, 30, 2023 was \$,154 and \$18,882 respectively. Future lease payments under the short term operating lease as of September 30, 2023 is \$72,039.

## 9. License Agreements

In September 2021, the Company licensed certain intellectual property from Klydon for the development, production distribution, marketing and sale of Mo-100. The license term was 999 years, unless terminated earlier by either party under certain provisions. Any development efforts improving the intellectual property performed by either Klydon or the Company was the property of Klydon. There were no upfront, milestone payments, nor royalties on product sales over the term of the license. Two individuals who are officers and board members of Klydon received warrants to purchase common stock of the Company. See Note 10.

In January 2022, the Company licensed certain intellectual property from Klydon for the development, production distribution, marketing and sale of uranium isotope U-235 (“U-235”). The license term was 999 years, unless terminated earlier by either party under certain provisions. Any development efforts improving the intellectual property performed by either Klydon or the Company was the property of Klydon. The Company paid an upfront fee of \$100,000, which was expensed to research and development expense. The Company was required to pay a nominal royalty per Kg of product sold plus 10% royalties on product net profits over the term of the contract. One of the officers, who is also a board member of Klydon, became a board member and consultant of ASP Isotopes Inc. and an employee of ASP Guernsey in January 2022.

In July 2022, ASP Isotopes UK Ltd (a subsidiary of the Company) entered into a license agreement with Klydon, as licensor, pursuant to which ASP Isotopes UK Ltd acquired from Klydon an exclusive license to use, develop, modify, improve, subcontract and sublicense certain intellectual property rights relating to the ASP technology for the production, distribution, marketing and sale of all isotopes produced using the ASP technology (the “Klydon license agreement”). The Klydon license agreement superseded and replaced the Mo-100 license and U-235 license described in the paragraphs above. The Klydon license agreement was royalty-free, had a term of 999 years and was worldwide for the development of the ASP technology and the distribution, marketing and sale of all isotopes. Future production of isotopes was limited to member countries of the Nuclear Suppliers Group. In connection with the Klydon license agreement the Company agreed to make an upfront payment of \$100,000 (to be included within the payments we make under the Turnkey Contract) and deferred payments of \$300,000 over 24 months, which was expensed to research and development expense. Klydon had the right to terminate the exclusivity of the Klydon license agreement in the event that the licensee ceases to carry on activities related to isotope enrichment for a period longer than 24 consecutive months. The \$400,000 due to Klydon was in accounts payable as of December 31, 2022.

In July 2022, ASP South Africa acquired assets comprising a dormant Silicon-28 aerodynamic separation processing plant from Klydon for ZAR6,000,000 (which at the then current exchange rate was approximately \$354,000), which was recorded to property and equipment, will be payable to Klydon on the later of 180 days of the acquisition and the date on which the assets generate any revenues of any nature.

On April 4, 2023, the Company perfected its interest under the Acknowledgement of Debt Agreement (see Note 7), pursuant to which the Company acquired certain intellectual property from Klydon (“Klydon Acquisition”). The Company concluded that the Klydon Acquisition is accounted for under ASC 805, Business Combinations as an asset acquisition since the assets acquired were concentrated in a single identifiable asset from a related party. In conjunction with the Klydon Settlement, the Company recorded an increase to additional paid-in capital for the settlement of all liabilities owed to Klydon at the time of settlement totaling \$626,223.

## **10. Stockholders’ Equity**

### ***Preferred stock***

ASP Isotopes Inc. had 10,000,000 shares of preferred stock authorized, of which no shares were issued and outstanding as of September 30, 2023 and December 31, 2022.

In conjunction with the formation of Enlightened Isotopes in March 2023, in exchange for 3,000,000 shares of common stock held by an officer and scientific advisor of ASP Isotopes Inc., Enlightened Isotopes issued 2,500 shares of convertible preferred stock. These shares convert into common stock of Enlightened Isotopes at any time upon the election of the preferred stockholders such that these two investors will own 20% of the then outstanding shares on a fully diluted basis. The Company will report the non-controlling interest of future net income or loss on the consolidated balance sheet and statement of operations and comprehensive loss.

### ***Common stock***

The Company had 500,000,000 shares of common stock authorized, of which 38,348,184 shares were issued and outstanding as of September 30, 2023. Common stockholders are entitled to one vote for each share of outstanding common stock held at all meetings of stockholders and written actions in lieu of meetings. Common stockholders are entitled to receive dividends for each share of outstanding common stock, if and when declared by the Board. No dividends have been declared or paid by the Company through September 30, 2023.

During 2022, prior to the IPO, the Company issued 1,559,780 shares of common stock at \$2.00 per share for gross proceeds of \$3,119,560. The Company incurred \$255,965 in cash issuance costs and is required to issue 120,491 shares of common stock to the placement agent with an initial fair value of \$240,982. In October 2022, the Company amended its agreement with the placement agent for the shares issued from November 2021 through the first nine months of 2022. The shares of common stock issuable to the placement agent was reduced from 120,491 shares to 57,250 shares. The fair value of the 57,250 shares issuable to the placement agent as of December 31, 2022 was \$90,455. The fair value of the 57,250 shares issuable to the placement agent just prior to settlement in March 2023 was \$5,570, resulting in a change in fair value of share liability of \$14,885 for the three months ended March 31, 2023. In March 2023, the Company settled this share liability by issuing 57,250 shares of common stock.

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In October 2022, the Company was required to issue shares of common stock with a fair value totaling \$0,455 as at December 31, 2022. The fair value of these shares issued in March 2023 was \$75,570. The resulting change in fair value income of the share liability \$4,885 for the three and nine months ended September 30, 2023.

In November 2022, the Company was required to issue shares of common stock with a then fair value totaling \$0,000 to a consultant. The fair value of these shares issued in August 2023 was \$18,125. The resulting change in fair value income of the share liability \$1,875 for the three and nine months ended September 30, 2023.

In November 2022, the Company completed its IPO, selling an aggregate of 1,250,000 shares of common stock at a price to the public of \$4.00 per share, not including 187,500 shares of common stock issuable pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. The Company received net proceeds from the IPO, after deducting underwriting discounts and commissions but before deducting offering costs, of approximately \$3.8 million.

In February 2023, the Company was required to issue an aggregate of 100,000 shares of common stock to two consultants. The Company determined that the fair value of these two awards was \$1.55 and \$1.90 per share, respectively, for a total value of \$172,500. The fair value of these shares issued in August 2023 to the two consultants was \$145,000. The resulting change in fair value expense of the share liability was \$8,200 and income of \$27,500 for the three and nine months ended September 30, 2023, respectively.

In March 2023, the Company was required to issue an aggregate of 100,000 shares of restricted common stock pursuant to a settlement agreement that vests immediately. The Company determined that the fair value of this award was \$0.94 per share for a total value of \$93,700. The fair value of these shares issued in August 2023 was \$145,000. The resulting change in fair value of the share liability expense was \$8,200 and \$51,300 for the three and nine months ended September 30, 2023, respectively.

In March 2023, an officer and scientific advisor of the Company exchanged an aggregate of 3,000,000 shares of ASP Isotopes Inc. common stock for 2,500 shares of Enlighted Isotopes convertible preferred stock. In conjunction with the exchange, Enlighted Isotopes transferred the common shares of ASP Isotopes Inc. to ASP Isotopes and then ASP Isotopes immediately cancelled all 3,000,000 shares. The Company will report the non-controlling interest of future net income or loss on the consolidated balance sheet and statement of operations and comprehensive loss.

In March 2023, the Company's non-employee board members agreed to receive the 2022 cash director fees totaling \$45,000 in shares of common stock. As of September 30, 2023, these shares had yet to be issued.

In March 2023, the Company issued 3,164,557 shares of the Company's common stock at a purchase price of \$1.58 per share and warrants to purchase up to an aggregate of 3,164,557 shares of its common stock with an exercise price of \$1.75 per share for gross proceeds of \$5.0 million. The Company incurred \$506,390 in cash issuance costs and issued warrants to purchase up to an aggregate of 221,519 shares of common stock with an exercise price of \$1.975 per share to the placement agent with an initial fair value of \$179,116.

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In May 2023, the Company was required to issue an aggregate of 100,000 shares of restricted common stock pursuant to a consultant. The Company determined that the fair value of this award was \$0.65 per share for a total value of \$65,100. The fair value of these shares issuable to the consultant was \$95,000 as of September 30, 2023 resulting in a change in fair value expense of the share liability of \$38,200 and \$29,900 respectively for the three and nine months ended September 30, 2023. As of September 30, 2023, these shares had yet to be issued.

In May 2023, the Company was required to issue an aggregate of 50,000 shares of restricted common stock pursuant to a consultant. The company determined that the fair value of this award was \$0.62 per share for a total value of \$30,900. The fair value of these shares issuable was \$47,500 as of September 30, 2023, resulting in a change in fair value expense of share liability of \$16,600 for the three and nine months ended September 30, 2023. As of September 30, 2023, these shares had yet to be issued.

In July 2023, the Company was required to issue an aggregate of 150,000 shares to consultants. The company determined that the fair value of these awards was \$1.21 for a total value of \$181,500. The fair value of the 100,000 and 50,000 shares issued in August 2023 was \$248,000. This resulted in a change in fair value expense of the share liability of \$66,500 for the three and nine months ended September 30, 2023.

In August 2023, the Company was required to issue an aggregate of 100,000 shares of restricted common stock pursuant to consultants. The company determined that the fair value of this award was \$1.26 per share for a total value of \$126,000. The fair value of the shares issued in August was \$145,000. This resulted in a change in fair value expense of the share liability of \$19,000 for the three and nine months ended September 30, 2023.

	Share Liability as of December 31, 2022	New Share Liabilities in 2023	Mark to Market Adjustments in 2023	Liabilities Settled in 2023	Share Liability as of September 30, 2022
Share liabilities originated in 2022	\$ 140,455	\$ -	\$ (46,760)	\$ (93,695)	\$ -
Share liabilities originated in 2023	-	669,700	155,800	(683,000)	\$ 142,500
	\$ 140,455	\$ 669,700	\$ 109,040	\$ (776,695)	\$ 142,500

Subsequent to the reporting date, in October 2023, the Company entered into Securities Purchase Agreements with certain institutional and other accredited investors and certain directors of the Company to issue and sell an aggregate of 9,952,510 shares of the Company's common stock, for aggregate cash consideration of \$9,129,461, as follows: (i) 8,459,093 shares of Common Stock to investors at a purchase price per share of \$0.9105, (ii) 1,190,239 shares of Common Stock to investors at a purchase price per share of \$0.9548, and (iii) 303,178 shares of Common Stock to directors at a purchase price per share of \$0.96.

**Common Stock Warrants**

The fair values of the warrants issued in the nine months ended September 30, 2023 were estimated based on the Black-Scholes model, using the following assumptions:

Expected volatility	60.3%
Weighted-average risk-free rate	3.44%
Expected term in years	5.5
Expected dividend yield	0%

In January 2022, warrants to purchase 7,230,822 shares of common stock were net share settled into 7,194,847 shares of common stock per the terms of the underlying warrant agreements. No warrants were exercised in the nine months ended September 30, 2023.

**11. Stock Compensation Plan****Equity Incentive Plan**

In October 2021, the Company adopted the 2021 Stock Incentive Plan (“2021 Plan”) that provided for the issuance of common stock to employees, nonemployee directors, and consultants. Recipients of incentive stock options are eligible to purchase shares of common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The 2021 Plan provided for the grant of incentive stock options, non-statutory stock options, restricted stock, restricted stock units, stock awards and stock appreciation rights. The maximum contractual term of options granted under the 2021 Plan is ten years. The maximum number of shares initially available for issuance under the 2021 Plan was 6,000,000. No further options are available to be issued under the 2021 Plan.

In November 2022, the Company adopted the 2022 Equity Incentive Plan (“2022 Plan”) that provides for the issuance of common stock to employees, nonemployee directors, and consultants. Recipients of incentive stock options are eligible to purchase shares of common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The 2022 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock, restricted stock units, stock awards and stock appreciation rights. The maximum contractual term of options granted under the 2022 Plan is ten years. The number of shares of the Company’s common stock initially reserved for issuance under the 2022 Plan is equal to 5,000,000, subject to an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2023 and continuing until, and including, the fiscal year ending December 31, 2033, equal to the lesser of 5% of the number of shares of the Company’s common stock outstanding on such date or an amount determined by the Company’s board of directors. As of September 30, 2023, 488,606 shares remain available for future grant under the Plan.

**Stock Options**

The following table sets forth the activity for the Company’s stock options during the periods presented:

	Number of Options	Weighted- Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	2,901,000	\$ 1.91	9.4	\$ 199,500
Granted	-	-	-	-
Forfeited	(86,667)	\$ 2.00		
Outstanding as of September 30, 2023	<u>2,814,333</u>	<u>\$ 1.91</u>	<u>8.6</u>	<u>\$ 105,000</u>
Exercisable as of September 30, 2023	<u>1,501,177</u>	<u>\$ 1.88</u>	<u>8.6</u>	<u>\$ 69,609</u>
Vested or expected to vest as of September 30, 2023	<u>2,814,333</u>	<u>\$ 1.91</u>	<u>8.6</u>	<u>\$ 105,000</u>

For the nine months ended September 30, 2023, no options were granted. For the nine months ended September 30, 2022, the Company granted 2,751,000 options with an exercise price of \$ 2.00 per share that vest monthly over one to three years. The weighted-average grant date fair value of options granted for the nine months ended September 30, 2022 was \$1.18.

The Company recorded stock compensation from options of \$207,253 and \$352,910 for the three months ended September 30, 2023 and 2022, respectively. The Company recorded stock compensation from options of \$773,238 and \$559,458 for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, there was \$ 1,529,455 of unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan, which is expected to be recognized over a weighted average period of approximately 1.5 years.

**Stock Awards**

In October 2021, the Company issued 1,500,000 shares of restricted common stock to its Chief Executive Officer. The number of shares that vest is dependent on achieving certain performance conditions and dependent market conditions upon the third anniversary from the date of grant. The Company determined that the fair value of this award was \$0.25 per share for a total value of \$375,000. Upon reaching the performance condition, the Company will recognize stock compensation expense over the remaining measurement period. No stock compensation was recorded for this award for the three and nine months ended September 30, 2023 and 2022.

In October 2021, the Company issued 600,000 shares of restricted common stock to a consultant who is also a member of the board of directors, that vest annually over three years. The Company determined that the fair value of this award was \$0.25 per share for a total value of \$150,000. The consulting agreement also included future awards of common stock for continued service, however in March 2023, the consulting agreement was amended and these future awards were cancelled.

In July 2022, the Company issued 600,000 shares of restricted common stock to a consultant who is also a member the of board of directors, that vest quarterly over one year. The Company determined that the fair value of this award was \$2.00 per share for a total value of \$1,200,000.

In July 2022, the Company issued 100,000 shares of restricted common stock to a consultant, that vests on the one-year anniversary of the grant. The Company determined that the fair value of this award was \$2.00 per share for a total value of \$200,000.

In November 2022, the Company issued 3,000,000 shares of restricted common stock to certain employees and directors, that vest two to four years from the date of the grant. The Company determined that the fair value of these awards was \$2.63 per share for a total value of \$7,890,000.

In December 2022, the Company issued an aggregate of 1,550,000 shares of restricted common stock to its Chief Executive Officer and Chairman, Interim Chief Financial Officer and a director that vest quarterly over one year from the date of the grant. The Company determined that the fair value of these awards was \$1.58 per share for a total value of \$2,449,000.

In March 2023, the Company issued an aggregate of 1,256,750 shares of restricted common stock to its Chief Executive Officer and Chairman and a director that vests quarterly over one year from the date of the grant. The Company determined that the fair value of these awards was \$1.80 per share for a total value of \$2,262,150.

In August 2023, the Company issued 500,000 shares of restricted common stock pursuant to one employee and one director for employment services. The Company determined that the fair value of these awards totaled \$165,000 and \$244,000, respectively and will be recognized over the two year service periods.

The Company recorded stock compensation from stock awards totaling \$1,864,537 and \$362,500 for the three months ended September 30, 2023 and 2022, respectively. The Company recorded stock compensation from stock awards totaling \$5,817,338 and \$387,500 for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, there is \$1,529,455 of unrecognized compensation cost related to the non-vested portion of stock awards that is expected to be recognized over the next 1.5 years.

The following table summarizes vesting of restricted common stock:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value Per Share</b>
Unvested as of December 31, 2022	7,000,000	\$ 1.75
Granted	1,756,750	\$ 1.52
Vested	(2,340,876)	\$ 1.74
Unvested as of September 30, 2023	<u>6,415,874</u>	<u>\$ 1.58</u>

**Stock-based Compensation Expense**

Stock-based compensation expense for all stock awards recognized in the accompanying consolidated statements of operations is as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
General and administrative	\$ 1,978,904	\$ 624,006	\$ 6,311,890	\$ 840,131
Research and development	92,886	91,404	278,686	106,827
<b>Total</b>	<b>\$ 2,071,790</b>	<b>\$ 715,410</b>	<b>\$ 6,590,576</b>	<b>\$ 946,958</b>

**11. Net Loss Per Share**

The Company has reported losses since inception and has computed basic net loss per share attributable to common stockholders by dividing net loss attributable to common stockholders by the weighted-average number of shares of Common Stock outstanding for the period, without consideration for potentially dilutive securities. The Company computes diluted net loss per share of Common Stock after giving consideration to all potentially dilutive shares of common stock, including options to purchase common stock and warrants to purchase common stock, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential shares of Common Stock have been anti-dilutive and basic and diluted loss per share were the same for all periods presented.

The following table sets forth the computation of basic and diluted net loss per share for the three and nine months ended September 30, 2023 and 2022:

	<b>Three Months Ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Numerator:				
Net loss	\$ (4,222,483)	\$ (1,956,230)	\$ (12,123,907)	\$ (3,640,988)
Denominator:				
Weighted average common stock outstanding, basic and diluted	31,147,749	30,107,127	29,954,321	28,642,533
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.06)	\$ (0.40)	\$ (0.13)



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The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive:

	As of September 30,	
	2023	2022
Options to purchase common stock	2,814,333	2,901,000
Warrants to purchase common stock	3,386,076	-
Restricted stock	6,415,874	-
Total shares of common stock equivalents	12,616,283	2,901,000

## 12. Income Taxes

The Company has no income tax expense due to operating losses incurred for the three and nine months ended September 30, 2023 and 2022. The Company has provided a full valuation allowance on the net deferred tax asset because management has determined that it is more-likely-than-not that the Company will not earn income sufficient to realize the deferred tax assets during a future period.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition threshold to be recognized. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on the Company's balance sheets and has not recognized interest and/or penalties in the statements of operations and comprehensive loss for the three and nine months ended September 30, 2023. Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgment based upon new information may lead to changes in recognition, derecognition, and measurement. Adjustments may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitations barring an assessment for an issue. As of September 30, 2023 and December 31, 2022, there were no uncertain tax positions.

As of September 30, 2023, the Company did not recognize any interest and penalties associated with unrecognized tax benefits. Due to net operating losses incurred, tax years from inception remain open to examination by the Federal and State taxing jurisdictions to which we are subject. The Company is not currently under Internal Revenue Services (IRS), state or local tax examination.

Ownership changes, as defined in the IRC, may limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income pursuant to IRC Section 382 or similar provisions. Subsequent ownership changes could further affect the limitation in future years. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and because there could be additional changes in control in the future. As a result, the Company is not able to estimate the effect of the change in control, if any, on the Company's ability to utilize net operating loss and research and development credit carryforwards in the future.

## 13. Subsequent Events

The Company has evaluated subsequent events through November 14, 2023, the date on which the accompanying financial statements were issued and concluded that no subsequent events have occurred that require disclosure except as noted below or in Note 10.

### *PET Labs Share Purchase Agreement*

In October 2023, ASP Isotopes Inc. entered into a Share Purchase Agreement ("SPA") with Nucleonics Imaging Proprietary Limited ("Nucleonics"), a company incorporated in South Africa, to purchase ordinary shares in Nucleonics' wholly-owned subsidiary, Pet Labs Pharmaceuticals Proprietary Limited ("PET Labs"), a company incorporated in South Africa and dedicated to nuclear medicine and the science of radiopharmaceutical production.

Per the SPA, ASP Isotopes Inc. has agreed to purchase from Nucleonics 51% of the issued share capital of PET Labs ("Initial Shares") ASP Isotopes Inc. will pay a total of \$2,000,000 for the Initial Shares in two instalments. The first instalment of \$500,000 was paid in November 2023. The second instalment of \$1,500,000 is payable upon demand by Nucleonics after October 27, 2024.

In addition, ASP Isotopes Inc. has an option to purchase from Nucleonics the remaining 49% of the issued share capital of PET Labs ("Option Shares") that expires on January 31, 2027. The option is only exercisable if the Initial Shares have been paid in full. Upon ASP Isotopes Inc. exercising its option to purchase the Option Shares ASP Isotopes has agreed to pay an additional \$2,200,000 to Nucleonics.

As of the date on which the accompanying financial statements were issued, the Company is still evaluating the accounting and financial reporting requirements of this transaction.

## 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 together with our condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q. 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 and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Cautionary Note Regarding Forward-Looking Statements."*

### Overview

We are a pre-commercial stage advanced materials company dedicated to the development of technology and processes that, if successful, will allow for the enrichment of natural isotopes into higher concentration products, which could be used in several industries. Our proprietary technology, the Aerodynamic Separation Process ("ASP technology"), originally developed by Klydon Proprietary Ltd ("Klydon") is designed to enable the production of isotopes used in several industries. Our initial focus is on the production and commercialization of enriched Carbon-14 ("C-14"), Molybdenum-100 ("Mo-100") and Silicon-28 ("Si-28"). We have commissioned a first isotope enrichment plant for the enrichment of C-14 located in Pretoria, South Africa, and anticipates completion and commissioning of a second multi-isotope enrichment plant in Pretoria, South Africa during the first half of 2023. In addition, we have started planning additional isotope enrichment plants. We believe the C-14 we may develop using the ASP technology could be used in the development of new pharmaceuticals and agrochemicals. We believe the Mo-100 we may produce using the ASP technology could have significant potential advantages for use in the preparation of nuclear imaging agents by radiopharmacies and others in the medical industry. We believe the Si-28 we may produce using the ASP technology may be used to develop advanced semiconductors and in quantum computing.

We are also developing quantum enrichment technology to produce enriched Ytterbium-176, Nickel-64, Lithium 6, Lithium7 and Uranium-235 ("U-235"). Quantum enrichment is an advanced isotope enrichment technique that is currently in development that uses lasers. We believe that the U-235 we may develop using quantum enrichment technology may be commercialized as a nuclear fuel component for use in the new generation of HALEU-fueled small modular reactors that are now under development for commercial and government uses.

On November 15, 2022, we completed an IPO of our common stock and issued and sold 1,250,000 shares of common stock at a public offering price of \$4.00 per share, resulting in net proceeds of \$3.8 million after deducting underwriting discounts and commissions and offering expenses.

In March 2023, we issued 3,164,557 shares of our common stock at a purchase price of \$1.58 per share and warrants to purchase up to an aggregate of 3,164,557 shares of our common stock with an exercise price of \$1.75 per share for gross proceeds of \$5.0 million. We incurred \$506,390 in cash issuance costs and issued warrants to purchase up to an aggregate of 221,519 shares of common stock with an exercise price of \$1.975 per share to the placement agent with an initial fair value of \$179,116.

In October 2023, the Company entered into Securities Purchase Agreements with certain institutional and other accredited investors and certain directors of the Company to issue and sell an aggregate of 9,952,510 shares of the Company's common stock, for aggregate cash consideration of \$9,129,461, as follows: (i) 8,459,093 shares to investors at a purchase price per share of \$0.9105, (ii) 1,190,239 shares to investors at a purchase price per share of \$0.9548, and (iii) 303,178 shares to directors at a purchase price per share of \$0.96. The Company incurred issuance costs equivalent to 5% of the gross proceeds from new investors which was settled in stock through the issuance of 472,582 shares to the placement agent.

## Acquisitions of Assets and Agreements with Klydon

To date, we have purchased certain assets of Molybdos Proprietary Limited, a South Africa company (Molybdos), and entered into a number of agreements with Klydon (Pty) Limited, a South Africa company (Klydon). Below is a summary of the key terms for our former licenses and other agreements with Klydon.

**Acquisition of Molybdos Assets.** On September 30, 2021, our subsidiary, ASP Isotopes South Africa (Proprietary) Limited (“ASP South Africa”), participated in and was declared the winner of a competitive auction process under Section 45 of the South Africa Consumer Protection Act, 2008 related to the sale and assignment of the assets of Molybdos (the “Molybdos Business Rescue Auction”). On October 12, 2021, ASP South Africa acquired the assets of Molybdos for ZAR 11,000,000 (which at the then current exchange rate was approximately \$734,000), plus value added tax (VAT) levied by the government of South Africa at the rate of 15% and auctioneers’ commission at the rate of 10%.

**Acquisition of Silicon-28 Plant Assets.** On July 26, 2022, we acquired assets comprising a dormant Silicon-28 aerodynamic separation processing plant from Klydon for ZAR 6,000,000 (which at the then current exchange rate was approximately \$364,000), which will be payable to Klydon on the later of 180 days of the acquisition and the date on which the assets generate any revenues of any nature.

**Omnibus Klydon License.** On July 26, 2022, ASP Isotopes UK Ltd, as licensee, entered into a license agreement with Klydon, as licensor, pursuant to which ASP Isotopes UK Ltd acquired from Klydon an exclusive license to use, develop, modify, improve, subcontract and sublicense certain intellectual property rights relating to the ASP technology for the production, distribution, marketing and sale of all isotopes produced using the ASP technology (the “Klydon license agreement”). The intellectual property rights granted to us through the Klydon license agreement included all existing and/or future proprietary rights of Klydon relating to the ASP technology, whether or not such rights have been registered, including the copyright, designs, know-how, patents and trademarks (although Klydon currently has no such patents, patent applications or copyrights). The Klydon license agreement was royalty-free, had a term of 999 years and was worldwide for the development of the ASP technology and the distribution, marketing and sale of isotopes. Future production of isotopes is limited to member countries of the Nuclear Suppliers Group. In connection with the Klydon license agreement, we agreed to make an upfront payment of \$100,000 (to be included within the payments we made under the Turnkey Contract (described below) and deferred payments of \$300,000 over 24 months. Effective April 4, 2023, pursuant to the Acknowledgement of Debt Agreement described below, we acquired the ASP technology, among other things, from Klydon, and the Klydon license agreement is no longer in effect.

**Turnkey Contract.** On November 1, 2021, ASP South Africa and Klydon, as the contractor, entered into a contract under which Klydon has been appointed to supply to ASP South Africa a complete turnkey isotope enrichment plant (the “Turnkey Contract”). The activities to be undertaken or performed by Klydon include: taking control of the assets acquired in the Molybdos Business Rescue Auction; the design of an isotope enrichment facility; the supply of components, equipment and labor required for the construction; the installation, testing and commissioning of the isotope enrichment plant; securing all required approvals, regulatory authorizations and other required consents for the operation of the plant; providing training to local ASP Isotopes South Africa (Proprietary) Limited personnel to enable them to operate the plant going forward; and providing warranties in relation to the performance targets of the plant which are required to be met. Klydon was responsible for liaising with the relevant South African authorities, including the South African Non Proliferation Council, the Nuclear Suppliers Group and International Atomic Energy Agency to ensure that the Turnkey Contract and the isotope enrichment plant are compliant with international laws and guidelines.

**Acknowledgement of Debt Agreement.** Klydon performed a portion of the services required under the Turnkey Contract described above; however, services were incomplete and many of the services were not completed within the time frame required. As a result, Klydon and ASP South Africa entered into an Acknowledgement of Debt Agreement dated November 30, 2022, whereby Klydon (i) agreed to pledge its assets (the “Pledged Assets”) to ASP South Africa to secure its performance of the Turnkey Contract by December 31, 2022, and (ii) acknowledged that ASP South Africa would suffer damages in the amount of \$6,050,000 (“Damage Amount”) should it fail to perform. Under the Acknowledgement of Debt Agreement, the Pledged Assets would serve as collateral for Klydon’s obligation to pay the Damage Amount should Klydon fail to perform. In connection therewith, also on November 30, 2022, ASP South Africa and Klydon entered into a Deed of Security Agreement whereby, if Klydon failed to complete its obligations under the Turnkey Contract by December 31, 2022, all of Klydon’s rights of any nature to and interests of any nature in the Pledged Assets would be transferred to ASP South Africa. Klydon failed to complete its obligations under the Turnkey Contract by December 31, 2022.

On April 4, 2023, the Company perfected its interests in the assets under the Acknowledgement of Debt Agreement, pursuant to which the Company acquired the Pledged Assets, including certain intellectual property, from Klydon and settled all amounts due to Klydon, including the ZAR 6,000,000 for the acquisition of the Silicon-28 plant assets.

#### **Other Commercial Agreements**

Below is a summary of the key terms of our other commercial agreements.

**Lease for Molybdenum Processing Plant.** On October 12, 2021, ASP South Africa entered into an agreement of lease with the landlord of the facility located at 33 Eland Street, Koedoespoort Industrial, Pretoria where Klydon and its scientists and engineers will operate on our behalf the Molybdenum processing plant where gaseous Molybdenum compound will be treated (which process comprises several stages of compression and expansion during which the product is purified). The term of the lease ends on December 31, 2030.

**Political Risk Insurance Policy with Optio Group.** On October 25, 2021, ASP Guernsey entered into a contract of insurance to cover against political risk and expropriation to offset the risk of events detrimental to the company occurring in the Republic of South Africa for a period of three years. The insurer is Optio Group Limited which is 100% underwritten by one or more syndicates at Lloyd's of London. The specific risks covered in the policy are: (i) permanent and total abandonment of operations, (ii) deprivation of assets or shareholding, (iii) physical damage due to political violence, (iv) non-transfer or inconvertibility, (v) business interruption, (vi) non-honouring of arbitration award, and (vii) crisis management support. The limit of cover is equal to or in excess of the projected amount of investment required to complete the initial stage of the first planned Molybdenum enrichment plant. The limit of cover is capable of being increased and extended by mutual agreement with the insurer.

#### **Components of Results of Operations**

##### ***Operating Expenses***

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

##### ***Research and Development***

Our research and development expenses consist primarily of direct and indirect costs incurred in connection with the development activities for our future isotopes.

Direct costs include:

- external research and development expenses incurred under the Turnkey Contract; and
- costs related to designing the development processes of isotope production.

Indirect costs include:

- personnel-related costs, which include salaries, payroll taxes, employee benefits, and other employee-related costs, including stock-based compensation, for personnel engaged in research and development functions; and
- facilities and other various expenses.

Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

As described above, Klydon charged us for expenses associated with these research and development functions under the Turnkey Contract. We expect that our research and development expenses will increase substantially for the foreseeable future as we continue the development of our future isotopes. We cannot determine with certainty the timing of initiation, the duration or the completion costs of development activities. Actual development timelines, the probability of success and development costs can differ materially from expectations.

We will need to raise substantial additional capital in the future. In addition, we cannot forecast which future isotopes may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our research and development expenses may vary significantly based on a variety of factors, such as:

- the scope, rate of progress, expense and results of our development activities;
- the phase of development of our future isotopes;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and foreign regulatory authorities;
- significant and changing government regulation and regulatory guidance;
- the cost and timing of designing the development processes of isotope production;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work.

A change in the outcome of any of these variables with respect to the development of any of our future isotopes could significantly change the costs and timing associated with the development of that future isotope.

#### *General and Administrative*

General and administrative expenses consist primarily of personnel-related costs, which include salaries, payroll taxes, employee benefits, and other employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include legal fees relating to corporate matters, professional fees for accounting and consulting services and facility-related costs.

We expect that our ongoing general and administrative expenses will increase substantially for the foreseeable future to support our increased research and development activities and increased costs of operating as a public company and in building our internal resources. These increased costs will include increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor and public relations costs associated with operating as a public company.

**Results of Operations****Three Months Ended September 30, 2023 and 2022**

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	<b>Three Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development	\$ 239,199	\$ 745,461
General and administrative	3,707,311	1,208,319
Total operating expenses	<u>3,946,510</u>	<u>1,953,780</u>
Loss from operations	<u>(3,946,510)</u>	<u>(1,953,780)</u>
Other expense, net	<u>(275,973)</u>	<u>(2,450)</u>
Net loss	<u>\$ (4,222,483)</u>	<u>\$ (1,956,230)</u>

*Research and Development Expenses*

The following table summarizes our research and development expenses for the three months ended September 30, 2023 and 2022:

	<b>Three Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Personnel-related costs	113,336	203,139
License fees	-	391,455
Consulting, facility and other expenses	<u>125,863</u>	<u>150,867</u>
Total research and development expenses	<u>\$ 239,199</u>	<u>\$ 745,461</u>

Research and development expenses were \$239,199 for the three months ended September 30, 2023. These expenses include \$113,336 of personnel-related costs, including \$92,886 in stock-based compensation, and \$125,863 in consulting, facility and other expenses. Research and development expenses were \$745,461 for the three months ended September 30, 2022. These expenses include \$203,139 of personnel-related costs, including \$83,139 in stock-based compensation, \$391,455 of licensing fees and \$150,867 in consulting, facility and other expenses.

*General and Administrative Expenses*

General and administrative expenses were \$3,707,311 for the three months ended September 30, 2023. These expenses include \$2,484,637 of personnel-related costs, including \$1,978,904 in stock-based compensation, \$669,118 of professional services and legal-related fees and \$553,556 in facility and other corporate expenses. General and administrative expenses were \$1,208,319 for the three months ended September 30, 2022. These expenses include \$936,912 of personnel-related costs, including \$632,271 in stock-based compensation, \$116,467 of professional services and legal-related fees and \$154,940 in other corporate expenses.

**Nine Months Ended September 30, 2023 and 2022**

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development	\$ 699,413	\$ 1,191,901
General and administrative	11,319,465	2,448,091
Total operating expenses	<u>12,018,878</u>	<u>3,639,992</u>
Loss from operations	<u>(12,018,878)</u>	<u>(3,639,992)</u>
Other expense, net	(105,029)	(996)
Net loss	<u>\$ (12,123,907)</u>	<u>\$ (3,640,988)</u>

**Research and Development Expenses**

The following table summarizes our research and development expenses for the nine months ended September 30, 2023 and 2022:

	<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Personnel-related costs	369,136	442,827
License fees	-	491,035
Consulting, facility and other expenses	330,277	258,039
Total research and development expenses	<u>\$ 699,413</u>	<u>\$ 1,191,901</u>

Research and development expenses were \$699,413 for the nine months ended September 30, 2023. These expenses include \$369,136 of personnel-related costs, including \$278,686 in stock-based compensation, and \$330,277 in consulting, facility and other expenses. Research and development expenses were \$1,191,901 for the nine months ended September 30, 2022. These expenses include \$6,645 in costs directly related to the development of Mo-100, \$442,827 of personnel-related costs, including \$106,827 in stock-based compensation, \$491,035 for license fees and \$251,394 in consulting, facility and other expenses.

**General and Administrative Expenses**

General and administrative expenses were \$11,319,465 for the nine months ended September 30, 2023. These expenses include \$7,720,997 of personnel-related costs, including \$6,311,890 in stock-based compensation, \$2,165,926 of professional services and legal-related fees and \$1,432,542 in facility and other corporate expenses. General and administrative expenses were \$2,448,091 for the nine months ended September 30, 2022. These expenses include \$1,542,275 of personnel-related costs, including \$840,131 in stock-based compensation, \$629,799 of professional services and legal-related fees and \$276,017 in other corporate expenses.

**Liquidity and Capital Resources****Sources of Liquidity**

We have incurred net losses and negative cash flows from operations since our inception, and we expect to continue to incur significant and increasing net losses for the foreseeable future. We have principally financed our operations to date through the issuance of our common stock.

As of September 30, 2023, we had cash of \$2,286,805. We do not have any isotopes approved for sale, we have not generated any revenue from the sale of isotopes, and our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future isotopes.

### **Future Funding Requirements**

Based on our current operating plan, we estimate that our existing cash will not be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the date the financial statements are issued. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of developing isotopes is costly, and the timing of progress and expenses in these development activities is uncertain.

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

- the type, number, scope, progress, expansions, results, costs and timing of, our development activities for our future isotopes;
- the outcome, timing and costs of regulatory review of our future isotopes;
- the costs and timing of manufacturing for our future isotopes;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of establishing or securing sales and marketing and distribution capabilities, whether alone or with third parties, to commercialize future isotopes for which we may obtain regulatory approval, if any;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the costs of obtaining, expanding, maintaining and enforcing our patent and other intellectual property rights;
- costs associated with any products or technologies that we may in-license or acquire; and

Developing isotopes is a time-consuming, expensive and uncertain process that takes years to complete, and we may never achieve the necessary results required or obtain applicable regulatory approval for any isotopes or generate revenue from the sale of any future isotopes (assuming applicable regulatory approval is received). In addition, our future isotopes (assuming applicable regulatory approval is received) may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of isotopes that we do not expect to be commercially available in substantial quantities until at least 2024. If we receive permits and licenses to enrich U-235 (which in itself is highly uncertain), we do not expect U-235 to be commercially available for at least several years, if ever. As a result, we may need substantial additional financing to support our continuing operations and further the development of and commercialization of our future isotopes.

Until such time as we can generate significant revenue from sales of our future isotopes, if ever, we expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting severely diminished liquidity and credit availability, increased interest rates, inflationary pressures, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our future isotopes, future revenue streams or research programs or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our future isotopes even if we would otherwise prefer to develop and market such isotopes ourselves.



**Cash Flows**

The following table summarizes our sources and uses of cash for each of the periods presented:

	<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Cash used in operating activities	\$ (3,355,171)	\$ (2,077,859)
Cash used in investing activities	(1,190,157)	(3,570,632)
Cash provided by financing activities	4,493,610	2,850,549
Net change in cash	<u>\$ (51,718)</u>	<u>\$ (2,797,942)</u>

*Operating Activities.*

Net cash used in operating activities was \$3,355,171 for the nine months ended September 30, 2023, and was primarily due to our net loss of \$12,123,907, adjusted for stock-based compensation expense of \$6,590,576, expense related to the issuance of common stock to consultants of \$669,700 and amortization of right-of-use asset of \$49,173, partially offset by a change in fair value of share liability of \$109,040 and a \$1,349,278 change in our operating assets and liabilities.

Net cash used in operating activities was \$2,077,859 for the nine months ended September 30, 2022, and was primarily due to our net loss of \$3,640,988, adjusted for stock-based compensation expense of \$946,958 and amortization of right-of-use asset of \$51,624, and partially offset by a change in fair value of share liability of \$2,903 and a \$561,644 change in our operating assets and liabilities.

*Investing activities.*

Net cash used by investing activities was \$1,190,157 and \$3,570,632 for the nine months ended September 30, 2023 and 2022, respectively, and was comprised primarily of additional construction in progress.

*Financing Activities.*

Net cash provided by financing activities was \$4,493,610 for the nine months ended September 30, 2023, and was comprised of net proceeds of \$4,493,610 from the sale and issuance of 3,164,557 shares of our common stock in March 2023.

Net cash provided by financing activities was \$2,850,549 for the nine months ended September 30, 2022, and was comprised of net proceeds of \$2,863,595 from the sale and issuance of 1,559,780 shares of our common stock prior to our IPO and partially offset by the repayment of notes payable of \$13,046.

**Contractual Obligations and Commitments**

We lease our research and development facility in Pretoria, South Africa, under a lease with base monthly rent payment of approximately \$8,000 with a term expiring on December 31, 2030.

In November 2021, we entered into an agreement with Klydon Proprietary Limited (“Klydon”) to design and build a plant to enrich Molybdenum in South Africa. The initial phase of the project includes the building of a plant that can support the production of at least 5kgs of Mo-100, and is expected to be completed in the second half of 2023. The contracted cost for this phase is \$6,800,000. The second phase of the project includes the production to be increased to 20kgs of Mo-100 with an additional cost of \$6,000,000. We can modify the contract scope and overall costs and the contract can be cancelled by either party. As of September 30, 2023 and December 31, 2022, approximately \$7,233,000 has been paid under this contract and recorded as construction in progress within property and equipment.

Klydon performed a portion of the services required under the Turnkey Contract; however, services were incomplete, and many of the services were not completed within the time frame required. As a result, Klydon and ASP South Africa entered into an Acknowledgement of Debt Agreement dated November 30, 2022, whereby Klydon (i) agreed to pledge its assets (the “Pledged Assets”) to ASP South Africa to secure its performance of the Turnkey Contract by December 31, 2022, and (ii) acknowledged that ASP South Africa would suffer damages in the amount of \$6,050,000 (“Damage Amount”) should it fail to perform. Under the Acknowledgement of Debt Agreement, the Pledged Assets would serve as collateral for Klydon’s obligation to pay the Damage Amount should Klydon fail to perform. In connection therewith, also on November 30, 2022, ASP South Africa and Klydon entered into a Deed of Security Agreement whereby, if Klydon failed to complete its obligations under the Turnkey Contract by December 31, 2022, all of Klydon’s rights of any nature to and interests of any nature in the Pledged Assets would be transferred to ASP South Africa. Klydon failed to complete its obligations under the Turnkey Contract by December 31, 2022, however, we did not perfect our interests in the assets until April 4, 2023. We did not believe that the amounts owed by Klydon were realizable, nor did we know the timing of any recovery payments. Therefore, a loss recovery receivable was not recorded at any time prior to April 4, 2023.

On April 4, 2023, the Company perfected its interest under the Acknowledgement of Debt Agreement (see Note 6), pursuant to which the Company acquired certain intellectual property from Klydon (“Klydon Acquisition”). The Company concluded that the Klydon Acquisition will be accounted for under ASC 805, Business Combinations as an asset acquisition since the assets acquired were concentrated in a single identifiable asset from a related party.

Two individuals who are officers and board members of Klydon, one who is now an officer of ASP Isotopes Inc. and the other who is now a scientific advisor of ASP Isotopes Inc., received warrants to purchase our common stock.

In addition, we enter into contracts in the normal course of business with vendors for services and products for operating purposes. These contracts do not contain any minimum purchase commitments and generally provide for termination after a notice period and, therefore, are not considered long-term contractual obligations. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

#### **Off-Balance Sheet Arrangements**

During the period presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on a periodic basis. Our actual results may differ from these estimates.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Form 10-Q, we believe that the following accounting policies are critical to understanding our historical and future performance, as the policies relate to the more significant areas involving management’s judgments and estimates used in the preparation of our financial statements.

#### **Research and Development Costs**

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers will invoice us in arrears for services performed, based on a pre-determined schedule or when contractual milestones are met, but some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. If timelines or contracts are modified based upon changes in the protocol or scope of work to be performed, we modify our estimates and accruals accordingly on a prospective basis.

We base our expenses related to external research and development services on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are incorrect in any particular period.

### ***Stock-Based Compensation***

On October 3, 2021, our board of directors and stockholders approved the 2021 Plan. Under the 2021 Plan, stock-based awards are measured at fair value and recognized over the requisite service period. Forfeitures are accounted for in the period they occur. We estimate the fair value of each stock-based award on the date of grant using the Black-Scholes option pricing model, which requires the input of subjective assumptions:

- *Fair value of common stock.* Subsequent to the IPO the fair value of common stock is determined by the closing price on the date of grant.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities similar to the expected term of the awards.
- *Expected dividend yield.* We base the expected dividend yield assumption on the fact that we have never paid cash dividends and have no present intention to pay cash dividends and, therefore, used an expected dividend yield of zero.
- *Expected volatility.* Since, prior to our IPO, we were not yet a public company and did not have a trading history for our common stock, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Expected life.* The expected life represents the period of time that options are expected to be outstanding. Because we do not have historical exercise behavior, we determine the expected life assumption using the simplified method, for employees, which is an average of the contractual term of the option and its vesting period. The expected term for nonemployee options is equal to the contractual term.

### **Quantitative and Qualitative Disclosures About Market Risk**

#### ***Interest Rate Risk***

As of September 30, 2023 and December 31, 2022, our cash consists of cash in readily available checking accounts. We do not hold any short-term investments. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes. As of September 30, 2023 and December 31, 2022, we had no bank debt outstanding and are therefore not exposed to interest rate risk with respect to debt. We believe a hypothetical 100 basis point increase or decrease in interest rates during the period presented would not have had a material impact on our financial results.

#### ***Foreign Currency Risk***

Our expenses are generally denominated in U.S. dollars, but our operations are currently primarily located outside the United States, and we have entered into a number of contracts with vendors that are denominated in foreign currencies. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 100 basis point increase or decrease in exchange rates during the period presented would not have had a material impact on our financial results.

***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe that inflation and changing prices had a significant impact on our results of operations for the period presented herein.

**Emerging Growth Company and Smaller Reporting Company Status**

We are an “emerging growth company” under the JOBS Act, and as such, we can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed \$1.235 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period.

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 \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

**Item 4. Controls and Procedures.**

***Disclosure Controls and Procedures***

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as a result of a material weakness identified in our internal control over financial reporting, as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022, our disclosure controls and procedures were not effective as of September 30, 2023. In order to remediate the material weakness, management expects to hire additional accounting and finance resources or consultants with public company experience.

***Changes in Internal Control***

There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II-OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material legal proceedings.

### Item 1A. Risk Factors.

*An investment in our common stock involves a high degree of risk. In deciding whether to invest, you should carefully consider the following risk factors, as well as the financial and other information contained in this Quarterly Report on Form 10Q, including our condensed consolidated financial statements and related notes. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our stock to decline, which could cause you to lose all or part of your investment. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial also may become important factors that affect us.*

#### **Risks Related to Our Limited Operating History, Financial Position and Need for Additional Capital**

*We have a very limited operating history, and we have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable, or if we achieve profitability, we may not be able to sustain it.*

We were incorporated in September 2021, and we have a very limited operating history upon which you can evaluate our business and prospects. Our operations to date have been primarily focused on acquiring the assets of Molybdos (after participating in and being declared the winner of a competitive auction process under Section 45 of the *South Africa Consumer Protection Act, 2008* for ZAR 11,000,000, which at the then current exchange rate was approximately \$734,000) and in-licensing intellectual property rights related to the production of Molybdenum-100 (a non-radioactive isotope we believe may have applications primarily in the medical industry) and Uranium-235 (an isotope of uranium we believe may have application in the clean, efficient and carbon-free energy industry) using the ASP technology, organizing and staffing our company, research and development activities, business planning, raising capital, and providing general and administrative support for these operations. In July 2022, we acquired assets comprising a dormant Silicon-28 aerodynamic separation processing plant from Klydon for ZAR 6,000,000 (which at the then current exchange rate was approximately \$364,000), which will be payable to Klydon on the later of 180 days of the acquisition and the date on which the assets generate any revenues of any nature. We have not yet built a manufacturing plant that is producing commercial quantities of isotopes or even demonstrated the ability to produce commercial quantities of isotopes using the ASP technology or quantum enrichment technology. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the medical, technology and energy industries, including an ability to obtain applicable regulatory approvals, manufacture any isotopes at commercial scale, or conduct sales and marketing activities necessary for successful isotope commercialization. In addition, we have not yet sought any regulatory approval that may be necessary for application of Mo-100 that we may develop using the ASP process in the medical industry or the production of U-235 that we may develop using quantum enrichment. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing isotopes.

Investment in isotope enrichment technology is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential isotopes will fail to demonstrate adequate utility or effectiveness in the targeted application (or for medical indications, an acceptable safety profile), gain regulatory approval, if applicable, and become commercially viable. We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses since our inception in September 2021. For the nine months ended September 30, 2023 and 2022, we reported a net loss of \$12.1 and \$3.6 million, respectively. As of September 30, 2023, we had an accumulated deficit of \$19.7 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we:

- continue to invest in our research and development activities;
- seek applicable regulatory approvals for any future isotopes that we may successfully develop;
- experience any delays or encounter any issues with any of the above, including but not limited to failed research and development activities, safety issues or other regulatory challenges;
- hire additional engineering and production personnel and build our internal resources, including those related to audit, patent, other legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor and public relations costs;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- establish a sales, marketing and distribution infrastructure and establish manufacturing capabilities, whether alone or with third parties, to commercialize future isotopes (assuming receipt of applicable regulatory approvals), if any; and
- operate as a public company.

We expect limited commercial activity for our isotopes in the United States during the next two to three years, and we anticipate that most of our initial revenues from future sales of our Mo-100 will be derived from countries in Asia and EMEA (Europe, Middle East and Africa). To become and remain profitable, we must succeed in developing and eventually commercializing isotopes that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing research and development activities relating to our ASP technology, obtaining applicable regulatory approval for future isotopes, if any, and manufacturing, marketing and selling any future isotopes (assuming receipt of applicable regulatory approvals). We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with chemical isotopes separation, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our future isotopes or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***Our future prospects are tied directly to the end markets that use our isotopes, including the diagnostic medical imaging industry, and depend on our ability to successfully introduce our isotopes and adapt to a changing technology and medical practice landscape.***

The field of diagnostic medical imaging is dynamic, with new products, including equipment, software and products, continually being developed and existing products continually being refined. New hardware (scanners), software or agents in a given diagnostic modality may be developed that provide benefits superior to the then-dominant hardware, software and agents in that modality, resulting in commercial displacement of the existing radiotracers. For example, alternate scanners and radiotracers could be introduced. Similarly, changing perceptions about comparative efficacy and safety, as well as changing availability of supply, may favor one agent over another or one modality over another. In addition, new or revised appropriate use criteria developed by professional societies to assist physicians and other health care providers in making appropriate imaging decisions for specific clinical conditions can and have reduced the frequency of and demand for certain imaging modalities and imaging agents. Technological obsolescence in any of the medical imaging products that would use the Mo-100 that we plan to manufacture could have a material adverse effect on our business, results of operations, financial condition and cash flows.

The success of the company will depend in large part on the success of our management in integrating the acquired assets into the company. In October 2021, our subsidiary in South Africa acquired the assets of Molybdos after participating in and being declared the winner of a competitive auction process under Section 45 of the *South Africa Consumer Protection Act, 2008* for ZAR 11,000,000 (which at the then current exchange rate was approximately \$734,000), plus value added tax (VAT) levied by the government of South Africa at the rate of 15% and auctioneers' commission at the rate of 10%. We have not yet built a functioning Mo-100 or U-235 manufacturing plant or even demonstrated the ability to produce Mo-100 or U-235 using the assets acquired at the business rescue auction. We will not know whether the assets that we acquired will work according to our expectations until we have completed construction of the Molybdos plant. In July 2022, we acquired assets comprising a dormant Silicon-28 aerodynamic separation processing plant from Klydon located in Pretoria, South Africa for ZAR 6,000,000 (which at the then current exchange rate was approximately \$364,000). We intend to explore commercial opportunities for Silicon-28 and other light isotopes that may be produced using these assets. Our failure to achieve the integration of the acquired assets into the company and to commercialize the assets could result in our failure to realize the anticipated benefits of those acquisitions and could impair our results of operations, profitability and financial results.

***We currently have no sales, but we expect to be heavily dependent on a few large customers to generate a majority of our revenues. Our operating results could be adversely affected by a reduction in business with our future significant customers.***

We currently have no sales. However, we expect to rely on a limited number of customers to purchase any isotopes that we produce using the ASP technology or quantum enrichment under long-term contracts. Our future key customers may stop ordering our isotopes at any time or may become bankrupt or otherwise unable to pay. The loss of any of our future key customers could result in lower revenues than we anticipate and could harm our business, financial condition or results of operations.

***Our independent registered public accounting firm's report contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a "going concern."***

We incurred an accumulated deficit totaling \$19,676,973 through September 30, 2023. As of September 30, 2023, we had approximately \$2,286,805 in cash. We have yet to generate any revenues, and we anticipate that our losses will continue for the foreseeable future. We cannot assure you that our plans to commercialize isotopes that we may develop will be successful. These factors, among others, raise substantial doubt about our ability to continue as a going concern. The financial statements contained elsewhere in this report do not include any adjustments that might result from our inability to continue as a going concern. Unless we can begin to generate material revenue, we may not be able to remain in business. We cannot assure you that we will raise enough money or generate sufficient sales to meet our future working capital needs.

***We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations.***

We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we continue our research and development activities, seek applicable regulatory approvals for any future isotopes that we may successfully develop, and expand our organization by hiring additional personnel. In addition, following the closing of our IPO, we expect to incur additional costs associated with operating as a public company.

As of September 30, 2023, our cash was approximately \$2,286,805. Subsequent to the end of the most recent fiscal quarter, in October 2023, we sold an aggregate of 9,952,510 shares of our common stock, for aggregate cash consideration of approximately \$9.1 million. We believe, based on our current operating plan, that the net proceeds from our IPO and the private placements completed in March and October 2023, together with our existing cash and cash equivalents, will not be sufficient to fund our operations for at least the next 12 months from the date the financial statements are issued. Therefore, we may need to seek additional funds through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

In any event, we will require substantial additional capital to support our business operations as we pursue additional research and development activities related to our ASP technology and seek applicable regulatory approval of our any future isotopes, and otherwise to support our continuing operations. In addition, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution (assuming receipt of applicable regulatory approvals for our future isotopes). Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our future isotopes (assuming receipt of applicable regulatory approvals).

Additional funding may not be available on acceptable terms, or at all. We have agreed to pay the underwriter of our IPO “tail compensation” equal to 8.0% of the aggregate gross proceeds received by us from the sale of our Common Stock in any private or public offering or other financing or capital-raising transaction of any kind within the 12-month period from the date the financial statements are issued. As a result of severely diminished liquidity and credit availability, increased interest rates, inflationary pressures, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive. If we do not raise additional capital in sufficient amounts, we may be prevented from pursuing development and commercialization efforts, which will harm our business, operating results and prospects.

***We are subject to credit counterparty risk, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.***

The Company maintains cash balances at many financial institutions in multiple geographies. While the majority of cash balances are currently held in US\$ at U.S. financial institutions, our cash balances at those institutions may exceed the Federal Deposit Insurance Corporation (“FDIC”) insurance limit of \$250,000 per depositor per insured bank for each account ownership category. Our non-US banking counterparties might not have protections offered to their customers that are considered standard in the U.S. and even if such deposit insurances do exist, there is no guarantee that the insurer will honor those insurance policies. Although the Company currently believes that the financial institutions with whom it does business will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so. Any credit losses that may occur could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***Raising additional capital or acquiring or licensing assets by issuing equity or debt securities may cause dilution to our stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.***

We may plan to seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or future isotopes, or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market our future isotopes (assuming receipt of applicable regulatory approvals for our future isotopes) that we would otherwise develop and market ourselves.

#### **Risks Related to the Development and Commercialization of Our Future Isotopes**

***We are early in our research and development efforts for isotopes using the ASP technology and quantum enrichment. If we are unable to advance our future isotopes in development, obtain applicable regulatory approval and ultimately commercialize our future isotopes, or experience significant delays in doing so, our business will be materially harmed.***



We are still conducting research and development efforts using ASP technology to produce a wide array of isotopes, and have not yet produced any isotope at commercial scale. It is possible that the research and development, proof-of-concept, construction of a plant and commercialization will take longer than anticipated due to unexpected delays.

We also plan to begin researching the enrichment of uranium, which is a chemical element we believe may have application in the clean, efficient and carbon-free energy industry, using quantum enrichment. Quantum enrichment has never been used to produce isotopes at a commercial scale and the research that has been conducted using this technique has never been published. The IAEA has never inspected any facility that leverages this technology and there is no proof that this technology has ever been used to enrich uranium. There are significant regulatory hurdles associated with enabling our research and development efforts to enter the nuclear energy market. Multiple regulatory agencies need to provide approvals to allow us to proceed with the research and development necessary to show proof of concept to the market. If we demonstrate proof of concept, we anticipate that there will be further approvals needed to expand to a larger footprint to support commercial demand. We may not ever obtain these approvals. If we are unable to advance our future isotopes in development, obtain applicable regulatory approval and ultimately commercialize our future isotopes (assuming receipt of applicable regulatory approvals), or experience significant delays in doing so, our business will be materially harmed.

Our ability to generate product revenues will depend heavily on the success of our research and development activities, receipt of applicable regulatory approvals, and eventual commercialization of our future isotopes (assuming receipt of applicable regulatory approvals and compliance with all applicable regulatory authorities).

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our currently planned future isotopes, which may never occur.

We will have to be successful in a range of challenging activities, including completing research and development activities relating to our ASP technology, obtaining applicable regulatory approval for future isotopes, if any, and manufacturing, marketing and selling any future isotopes (assuming receipt of applicable regulatory approvals). We are only in the preliminary stages of most of these activities. If we are unable to succeed in these activities, we may not be able to generate sufficient revenue to continue our business.

***We rely on a limited number of suppliers to provide us components, and a material interruption in supply could prevent or limit our ability to execute our strategic plan and development programs in the expected timeframe.***

We depend upon a limited number of third-party suppliers for certain components required to construct the centrifuges and other equipment for the enrichment plants that are being constructed in Pretoria, South Africa. To date, we have been able to obtain the required components for our centrifuges without any significant delays or interruptions, except for certain delays related to COVID-19. If we lose any of these suppliers, we may be required to find and enter into supply arrangements with one or more replacement suppliers. Obtaining alternative sources of supply could involve significant delays and other costs, and these supply sources may not be available to us on reasonable terms or at all. Any disruption of supplies could delay completion of the enrichment plant in South Africa, which could adversely affect our ability to execute our strategic plan and development programs in the expected timeframe.

***Our business, financial and operating performance could be adversely affected by epidemics and other health-related issues.***

Global supply chains and the timely availability of components imported to South Africa from the United States, countries in Europe or other nations could be materially disrupted by quarantines, slowdowns or shutdowns, border closings, and travel restrictions resulting from the global pandemics or health crises. Further, impacts of pandemic-related impacts on our management and workforce, or our suppliers and contractors could adversely impact our business. While we have taken steps to protect our workforce and carry-on operations, we may not be able to mitigate all of the potential impacts. We anticipate increased costs related to, or resulting from pandemic due to, among other things, delays in supplier deliveries, impacts of travel restrictions, site access and quarantine requirements.

In the event that any future pandemic prevents our employees or our contractors from working in person at our facility in South Africa or our suppliers are unable to provide goods and services on the schedule we anticipated, the impacts on our schedule and costs could be material. The ultimate impact of a future pandemic on our operations, including our ability to execute our strategic plan and development programs in the expected timeframe, remains uncertain and will depend on future pandemic-related developments, including the duration of the pandemic and related government actions to prevent and manage disease spread, all of which are uncertain and cannot be predicted. The long-term impacts of a future pandemic on us, our contractors and suppliers that could impact our business are also difficult to predict but could adversely affect our business, results of operations, and prospects.

***Development activities at our facility in South Africa could be disrupted for a variety of reasons, which could prevent us from completing our development activities.***

A disruption in development activities at our facility in South Africa could have a material adverse effect on our business. Disruptions could occur for many reasons, including power outages, fire, natural disasters, weather, unplanned maintenance or other manufacturing problems, public health crises (including, but not limited to, the COVID-19 pandemic), disease, strikes or other labor unrest, transportation interruption, government regulation, political unrest or terrorism. Alternative facilities with sufficient capacity or capabilities may not be available, may cost substantially more or may take a significant time to start production, each of which could negatively affect our business and financial performance. South Africa struggles with limited electricity supply and regions of the country regularly undergo load-shedding, during which electricity is not available. This uncertain supply of electricity could impact our ability to operate and produce commercial products and could negatively affect the financial position of the Company.

***Risks associated with the development of the ASP technology for enrichment of isotopes could cause substantial delays in the development of our future isotopes.***

Prior to October 2021, as a company, we had no involvement with or control over the research and development of the ASP technology. We relied on Klydon to conduct such research and development in accordance with the applicable legal, regulatory and scientific standards. If the research and development processes or the results of the development programs associated with the ASP technology for development of isotopes prove to be unreliable, this could result in increased costs and delays in the development of our future isotopes, which could adversely affect any future revenue from these future isotopes (assuming receipt of applicable regulatory approvals).

***Regulatory approval for production and distribution of radiopharmaceuticals used for medical imaging and therapeutic treatments may involve a lengthy and expensive process with an uncertain outcome.***

Currently, the sale or use of Mo-100 is not regulated by a healthcare regulator, such as the FDA, European Medicines Agency (EMA) or comparable foreign regulatory authorities. However, products such as Mo-99 and Tc-99m that are produced from Mo-100 in a cyclotron or a linear accelerator are regulated by healthcare regulators. We expect radiopharmacies, hospitals, clinics and others in the medical community to produce the widely used medical radioisotope technetium-99m (Tc-99m) from the Mo-100 that we may produce using our ASP technology. Tc-99m is a diagnostic agent that is used by health care professionals with FDA-approved imaging devices to detect potential diseases like coronary artery disease and cancer, as well as evaluate lung, liver, kidney and brain function. When used with the appropriate diagnostic scanner device, such as a SPECT imaging system, the Tc-99m emits signals that are captured and produces an image of internal organs to detect various medical problems and contribute to diagnosis and treatment decisions. Our future customers who may use Mo-100 to produce radiopharmaceuticals will likely require regulatory approval for their products. To date, only one healthcare regulator (Canada) has approved the use of Tc-99m produced from Mo-100 via a cyclotron. Obtaining regulatory approval is expensive and can take many years to complete, and its outcome is inherently uncertain. Our customers' regulatory approval process may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the process.

In the future, we may need to obtain approval from the FDA, EMA or comparable foreign regulatory authorities prior to the sale of Mo-100 that we may produce using our ASP technology for use in medical imaging and therapeutic treatments. If we require FDA, EMA or other comparable foreign regulatory authorities to approve the sale of Mo-100 that we may produce using our ASP technology for medical imaging and therapeutic treatments, we must demonstrate the safety and utility or efficacy of our Mo-100. Obtaining regulatory approval is expensive and can take many years to complete, and its outcome is inherently uncertain. Our regulatory approval process may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the process.

Other isotopes that we intend to produce in the future may also require approvals from healthcare regulators such as FDA, EMA or comparable foreign regulatory authorities.

***Our success depends on our ability to adapt to a rapidly changing competitive environment in the nuclear industry.***

The nuclear industry in general, and the nuclear fuel industry in particular, is in a period of significant change, which could significantly transform the competitive landscape we face. The uranium and isotope enrichment sector is competitive. Changes in the competitive landscape may adversely affect pricing trends, change customer spending patterns, or create uncertainty. To address these changes, we may seek to adjust our cost structure and efficiency of operations and evaluate opportunities to grow our business organically or through acquisitions and other strategic transactions. We are actively considering, and expect to consider from time to time in the future, potential strategic transactions, which could involve, without limitation, changes in our capital structure, acquisitions and/or dispositions of businesses or assets, joint ventures or investments in businesses, products or technologies.

In connection with any such transaction, we may seek additional debt or equity financing, contribute or dispose of assets, assume additional indebtedness, or partner with other parties to consummate a transaction. Any such transaction may not result in the intended benefits and could involve significant commitments of our financial and other resources. Legal and consulting costs incurred in connection with debt or equity financing transactions in development are deferred and subject to immediate expensing if such a transaction becomes less likely to occur. If the actions we take in response to industry changes are not successful, our business, results of operations and financial condition may be adversely affected.

***We may explore strategic collaborations that may never materialize or may fail.***

We intend to accelerate the development of our enriched uranium program by selectively collaborating with energy companies in the United States. We intend to retain significant technology, economic and commercial rights to our programs in key geographic areas that are core to our long-term strategy. As a result, we intend to periodically explore a variety of possible additional strategic collaborations in an effort to gain access to additional resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

***If the market opportunities for our future isotopes are smaller than we estimate (even assuming receipt of any required regulatory approval), our business may suffer.***

We are currently focused on producing isotopes using our ASP technology to meet critical needs in society. We also plan to research the production of enriched uranium using quantum enrichment to meet the future needs of developers of U.S. advanced reactor technologies requiring HALEU. Our projections of the potential markets are based on estimates that have been derived from a variety of sources, including scientific literature and market research, and which may prove to be incorrect. We must be able to successfully acquire a significant market share in our potential markets to achieve profitability and growth. Customers may become difficult to gain access to, which would adversely affect our results of operations and our business.

***We face substantial competition, which may result in others discovering, developing or commercializing isotopes before or more successfully than us.***

The development and commercialization of radioisotopes and chemical elements is highly competitive. We face competition with respect to all the isotopes that we may produce using our ASP technology from established biotechnology and nuclear medicine technology companies and will face competition with respect to enriched uranium that we may seek to develop or commercialize in the future from innovative technology and energy companies. There are a number of large biotechnology and nuclear medicine technology companies that currently market and sell radioisotopes to radiopharmacies, hospitals, clinics and others in the medical community (Mo-99 is the active ingredient for Tc-99m-based radiopharmaceuticals used in nuclear medicine procedures). There are also a number of technology and energy companies that are currently seeking to develop HALEU. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

More established companies may have a competitive advantage over us due to their greater size, resources and institutional experience. In particular, these companies have greater experience and expertise in securing reimbursement, government contracts, relationships with key opinion leaders, obtaining and maintaining regulatory approvals and distribution relationships to market products. These companies also have significantly greater research and marketing capabilities than we do. If we are not able to compete effectively against existing and potential competitors, our business and financial condition may be harmed.

As a result of these factors, our competitors may complete development of isotopes before we are able to, which may limit our ability to develop or commercialize our future isotopes. Our competitors may also develop radioisotopes or technologies that are safer, more effective, more widely accepted and cheaper than ours, and may also be more successful than us in manufacturing and marketing their isotopes. These appreciable advantages could render our future isotopes obsolete or non-competitive before we can recover the expenses of their development and commercialization.

Mergers and acquisitions in the technology and energy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our programs.

***Even if one of the products that we or our customers may produce using the ASP technology receives regulatory approval, it may fail to achieve market acceptance by radiopharmacies, hospitals, clinics or others in the medical community necessary for commercial success.***

Even if the isotopes that we may produce using the ASP technology for the medical industry, or the radioisotopes that we expect our future customers to produce using the Mo-100 that we plan to offer, receives regulatory approval, the isotopes may fail to gain sufficient market acceptance by radiopharmacies, hospitals, clinics and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of isotopes that we may produce using the ASP technology, or the radioisotopes that our future customers may produce, will depend on a number of factors, including but not limited to:

- the potential advantages compared to alternative radioisotopes;
- the timing of market introduction of the product as well as competitive products;
- effectiveness of sales and marketing efforts;
- the strength of our relationships with radiopharmacies, hospitals, clinics and others in the medical community;
- the cost in relation to alternative radioisotopes;
- our ability to offer isotopes that we may produce using the ASP technology for sale at competitive prices;
- the convenience and ease of use compared to alternative radioisotopes;
- the willingness of radiopharmacies, hospitals, clinics and others in the medical community to try an innovative radioisotope; and
- the strength of marketing and distribution support;

Our efforts to educate radiopharmacies, hospitals, clinics and others in the medical community on the benefits of the isotopes that we may produce using the ASP technology may require significant resources and may never be successful.

Because we expect sales of Mo-100 that we may produce using the ASP technology (assuming receipt of applicable regulatory approvals for commercial sale) to generate substantially all of our revenues for the foreseeable future, the failure of the isotopes that we may produce using the ASP technology (assuming receipt of applicable regulatory approvals for commercial sale) to find market acceptance would harm our business and could require us to seek additional financing.

***We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.***

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If the isotopes that we may produce using our ASP technology gains market acceptance and our customers receive regulatory approval for the isotopes they produce, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize such product in the markets that we target, which will be expensive and time-consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We currently plan to independently commercialize the isotopes that we may produce using our ASP technology (assuming receipt of applicable regulatory approvals) in the United States by establishing a focused sales force and marketing infrastructure. We may opportunistically seek additional strategic collaborations to maximize the commercial opportunities for our medical isotopes business outside of the United States. We have no prior experience as a company in the marketing, sale and distribution of isotopes and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our isotopes, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

***Obtaining regulatory approval for either the Mo-100 that we may produce using the ASP technology, or the Tc-99m or Mo-99 that our future customers may produce using the Mo-100 that we plan to offer, in one jurisdiction does not mean that we or they will be successful in obtaining regulatory approval of such future products in other jurisdictions.***

Currently, the production and distribution of Mo-100 does not require any regulatory licenses from healthcare regulators. Healthcare regulators frequently change such requirements, and it is possible that in the future Mo-100 may be regulated as a healthcare product. Obtaining such regulatory licenses, if required, may be a timely and costly process and could materially impact our ability to commercialize the Mo-100 that we plan to offer. Obtaining regulatory approval of the Mo-100 that we may produce using the ASP technology in one jurisdiction does not guarantee that we will be able to obtain regulatory approval in any other jurisdiction. For example, even if the FDA grants regulatory approval of the Mo-100 that we may produce using the ASP technology, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of such future product in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of the Mo-100 that we may produce using the ASP technology. Products such as Tc-99m and Mo-99 that may be produced by our future customers using the Mo-100 that we plan to offer will likely require regulatory licenses in most regions. Healthcare regulators frequently change such requirements and it is unclear what each healthcare regulator will require. To date, only one region (Canada) has approved the use of Tc-99m that has been produced from Mo-100 in a cyclotron. Obtaining such regulatory licenses, if required, may be a timely and costly process and could materially impact the ability of our future customers to operate and use the Mo-100 that we plan to offer. Obtaining regulatory approval in one jurisdiction does not guarantee that we or they will be able to obtain regulatory approval in any other jurisdiction.

If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of the Mo-100 that we may produce using the ASP technology will be harmed.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any isotopes that we may develop.***

We face an inherent risk of product liability exposure if we commercialize any isotopes that we may develop. If we cannot successfully defend ourselves against claims that any such isotopes caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any isotopes that we may develop;
- loss of revenue;
- substantial monetary awards to patients;
- significant time and costs to defend the related litigation;
- a diversion of management's time and our resources;
- initiation of investigations by regulators;
- the inability to commercialize any isotopes that we may develop;
- injury to our reputation and significant negative media attention; and
- a decline in our share price.

Any product liability insurance coverage that we obtain and maintain may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any isotopes. Insurance coverage is increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

**Risks Related to Regulatory Compliance**

***Our business is and could become subject to a wide variety of extensive and evolving laws and regulations. Failure to comply with such laws and regulations and failure to obtain licenses, approvals and permits that may be required to execute on our strategy and develop our company's business could have a material adverse effect on our business.***

We are subject to a wide variety of laws and regulations relating to various aspects of our business, including with respect to the development of the ASP technology and our future isotopes, employment and labor, health care, tax, privacy and data security, health and safety, and environmental issues. Laws and regulations at the South African and foreign, federal, state and local levels frequently change, especially in relation to new and emerging industries, and we cannot always reasonably predict the impact of, or the ultimate cost of compliance with, current or future regulatory or administrative changes. In South Africa, our isotopes enrichment facilities are heavily regulated. South Africa is a signatory to the International Atomic Energy Agency (“IAEA”) conventions and has adopted safety standards from the IAEA. The design, construction and operation of the isotope enrichment plants are highly regulated and require government licenses, approvals and permits, and may be subject to the imposition of conditions. In some cases, these licenses, approvals and permits entail periodic reviews and inspections. While we and Klydon have received all licenses, approvals and permits required to build and operate our isotope enrichment facilities in South Africa, we cannot predict whether the conditions associated with such licenses, approvals and permits will be maintained. For example, each of Klydon and ASP Isotopes South Africa (Proprietary) Limited has received from the South African Council for The Non-Proliferation of Weapons of Mass Destruction (1) a registration certificate (which are valid for two years from the date of issuance) and (2) a Manufacturing and Services Permit. The permits provide that the Non-Proliferation Secretariat will conduct at least two industry visits in June and November (or as arranged) of every year. Each of the permits includes numerous conditions, including, for example, the obligation to keep the Council updated or informed on all separation projects at all times and at least through biannual declarations, which must be done through correspondence to the Council at the end of April and September every year. The permit issued to ASP Isotopes South Africa (Proprietary) Limited includes additional specific information requirements related to (i) the progress on the design and construction of the isotope separation plant, (ii) the progress on the manufacturing of isotope separation elements, and (iii) the commissioning of the plant. Each of the permits further provides that (i) any potential export of controlled goods and technology should be requested at an early stage through a Provisional Export Guidance Request, (ii) all isotope separation applications remain controlled regardless of the isotope atomic mass and will be dealt with on a case-by-case basis, and (iii) any ultimate transfer of these controlled goods and technology will be subject to the issuance of a permit by the Council as required in terms of the Non-Proliferation Act and related Government Notices and Regulations.

In addition, we cannot assure you that we will be able to obtain, on a timely basis or at all, any additional licenses, approvals and permits that may be required to execute on our strategy and develop our company’s business, including any such licenses, approvals and permits that may be required to introduce isotopes produced using ASP technology into the market and to begin the enrichment of uranium to demonstrate our capability to produce HALEU using the quantum enrichment technology.

Changes in law or the imposition of new or additional regulations or permit requirements that impact our business could negatively impact our performance in various ways, including by limiting our ability to collaborate with partners or customers or by increasing our costs and the time necessary to obtain required authorization. We monitor new developments and devote a significant amount of management’s time and external resources to compliance with these laws and regulations. We cannot assure you, however, that we are and will remain in compliance with all such requirements, and even when we believe we are in compliance, a regulatory agency may determine that we are not. In addition, we cannot assure you that we will be able to obtain all licenses, approvals and permits that may be required to execute on our strategy and develop our company’s business as currently contemplated. Failure by us, our employees, affiliates, partners or others with whom we work to comply with applicable laws and regulations or to obtain or comply with necessary licenses, approvals and permits could result in administrative, civil, commercial or criminal liabilities, including suspension or debarment from government contracts or suspension of our export/import privileges. Failure by us, our employees, affiliates, partners or others with whom we work to comply with the permits issued to us by the South African Council for The Non-Proliferation of Weapons of Mass Destruction could result in disruption of our development activities at our facility in South Africa, which could prevent us from completing our development activities.

***If technology developed for the purposes of enriching isotopes can be applied to the creation or development of weapons-grade materials, then our technology may be considered “dual use” technology and be subject to limitations on public disclosure or export.***

Our research and development of isotope enrichment is dedicated not only to producing isotopes for use in nuclear medical diagnostic procedures and concentrating uranium in the isotope uranium-235 for use in nuclear energy, but also to safeguarding any information with broad, dual-use potential that could be inappropriately applied. Enrichment is among the most sensitive nuclear technologies because it can produce weapon-grade materials. The ASP technology and quantum enrichment technology may be considered dual use and could be subject to export control, for example, under the Wassenaar Arrangement.

#### **Risks Related to Our Intellectual Property**

***Our intellectual property is not protected through patents or formal copyright registration. As a result, we do not have the full benefit of patent or copyright laws to prevent others from replicating the ASP technology.***

We have not yet protected our intellectual property rights through patents or formal copyright registration, and we currently have no patent applications pending. To date, we have relied exclusively on trade secrets and other intellectual property laws, non-disclosure agreements with our respective employees, consultants, vendors, potential customers and other relevant persons and other measures to protect our intellectual property, and intend to continue to rely on these and other means. As we intend to transition into the commercialization of isotopes, we envision our intellectual property and its security becoming more vital to our future. Until we protect our intellectual property through patent, trademarks and registered copyrights, we may not be able to protect our intellectual property and trade secrets or prevent others from independently developing substantially equivalent proprietary information and techniques or from otherwise gaining access to our intellectual property or trade secrets. In such an instance, our competitors could produce products that are nearly identical to ours, resulting in us selling less products or generating less revenue from our sales.

***We may be unable to adequately protect our intellectual property and proprietary rights and prevent others from making unauthorized use of our products and technology.***

Our success and competitiveness depend, in significant part, on our ability to protect our intellectual property rights, including the ASP technology and quantum enrichment technology and certain other practices, tools, technologies and technical expertise we utilize in designing, developing, implementing and maintaining processes used in the development of our future isotopes. To date, we have relied exclusively on trade secrets and other intellectual property laws, non-disclosure agreements with our respective employees, consultants, vendors, potential customers and other relevant persons and other measures to protect our intellectual property, and intend to continue to rely on these and other means.

For strategic reasons, we have not yet protected our intellectual property by filing patent applications related to our technology, inventions and improvements. Even if we filed patent applications and patents were granted, we cannot assure you we would be fully protected against third parties as those patents may not be sufficiently broad in their coverage, may not be economically significant, or may not provide us with any competitive advantage. Competitors may be able to design around any patents and develop isotope production techniques comparable or superior to the ASP technology or the quantum enrichment technology. Furthermore, the filing of a patent would entail the disclosure of our know-how, and breaches of patent rights related to a wrongful use of this know-how would be difficult to enforce in the international landscape. We believe that our intellectual property strategy differs significantly from the strategies of others involved in the medical isotope industry, many of whom have extensive patent portfolios and rely heavily on intellectual property registrations to enforce their intellectual property rights. As a result of this discrepancy in strategy, we may be at a competitive disadvantage with respect to the strength of our intellectual property protection. Unlike others involved in the medical isotope industry, who generally have patents providing exclusive control over their innovations, we have no recourse against any entity that independently creates the same technology as ours or legitimately reverse-engineers our technology.

We generally enter into non-disclosure agreements with our employees, consultants and other parties with whom we have strategic relationships and business alliances. We cannot, however, assure you that these agreements will be effective in controlling access to and distribution of our technology and proprietary information. Since we do not protect our intellectual property by filing patent applications, we rely on our personnel to protect our trade secrets, know-how and other proprietary information to a greater degree than we would if we had patent protection for our intellectual property. In any jurisdiction in which our research and development is not protected by similar agreements, there is no protection against the manufacture and marketing of identical or comparable research and development by third parties, who are generally free to use, independently develop, and sell our developments and technologies without paying license or royalty fees. Furthermore, our former employees may perform work for our competitors and use our know-how in performing this work. In the event we scale our business by hiring additional personnel and entering into contracts with third parties, the risks associated with breaches of non-disclosure agreements, confidentiality agreements and other agreements pertaining to our technology and proprietary information will increase, and such breaches could have an adverse effect on our business and competitive position.

We may come to believe that third parties are infringing on, or otherwise violating, our intellectual property or other proprietary rights. To prevent infringement or unauthorized use, we may need to file infringement and/or misappropriation suits, which are expensive and time-consuming, could result in meritorious counterclaims against us and would distract management's attention. In addition, in an infringement or misappropriation proceeding, a court may decide that one or more of our intellectual property rights is invalid, unenforceable, or both, in which case third parties may be able to use our technology without paying license fees or royalties. If we are unable to protect our intellectual property and proprietary rights, we may be unable to prevent competitors from using our own inventions and intellectual property to compete against us, and our business may be harmed.



***Our ASP technology may be found to infringe third party intellectual property rights.***

Third parties may in the future assert claims or initiate litigation related to their intellectual property rights in technology that is important to us, including the ASP technology. For example, on October 25, 2022, we received a letter (the “NMS Letter”) from a law firm acting on behalf of Norsk Medisinsk Syklotronsenter AS (“NMS”), asserting, among other things, that the grant of the former license to the ASP technology to us by Klydon violated a pre-existing exclusive sub-license to the ASP technology granted to Radfarma. In November 2023, we entered into a mutual release with NMS, Radfarma, and certain board members and shareholders of Radfarma related to the claims asserted in the NMS letter and other matters, without any payment or license of any rights by any party to the release. Any future claims alleging infringement of intellectual property rights with respect to the ASP technology on which our company relies could be time-consuming, resulting in costly arbitration or litigation and diversion of technical and management personnel, or require us to develop non-infringing technology or enter into license agreements. We cannot assure you that licenses will be available on acceptable terms, if at all. Furthermore, because of the potential for significant damage awards, which are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims resulting in large settlements. If any infringement or other intellectual property claim made against us by any third party is successful, or if we fail to develop non-infringing technology or license the proprietary rights on commercially reasonable terms and conditions, our business, operating results and financial condition could be materially adversely affected.

If the ASP technology infringes the proprietary rights of other parties, we could incur substantial costs, and we may have to take certain actions, including the following:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our technology or processes to avoid infringement;
- stop using the subject matter claimed to be held by others;
- pay damages; or
- defend arbitration, litigation or administrative proceedings which may be costly whether we win or lose (and may be prohibitively expensive, particularly for a company of our size), and which could result in a substantial diversion of our financial and management resources.

In addition, in an infringement proceeding, a court or tribunal may decide that our asserted intellectual property is not valid or is unenforceable. An adverse determination in any litigation, arbitration or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly. If our intellectual property rights are found to be invalid or unenforceable (in whole or in part), our ability to commercialize our future isotopes would suffer, and our business, results of operations and financial condition may be adversely affected.

***We may enter into collaboration agreements and strategic alliances, and we may not realize the anticipated benefits of such collaborations or alliances.***

We may wish to form collaborations in the future with respect to our future isotopes but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans. Research and development collaborations are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration and may not commit sufficient efforts and resources or may misapply those efforts and resources;
- collaborators may not pursue development and commercialization of future isotopes or may elect not to continue or renew development or commercialization programs;
- collaborators may delay, provide insufficient resources to, or modify or stop development activities for future isotopes;
- collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with our future isotopes;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our future isotopes, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital and personnel to pursue further development or commercialization of the applicable future isotopes; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

The development and potential commercialization of our future isotopes will require substantial additional capital to fund expenses. We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our future isotopes, including in territories outside the United States or for certain indications. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into an acquisition or in-license agreement or strategic partnership, we may not be able to realize the benefit of such transaction if we are unable to successfully integrate them with our existing operations and company culture or if there are materially adverse impacts on our or the counterparty's operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our future isotopes because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our future isotopes as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a future isotope, we can expect to relinquish some or all of the control over the future success of that future isotope to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, future isotopes and market opportunities. The collaborator may also consider alternative isotopes or technologies for similar applications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our future isotope. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. In addition, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such future isotope, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such future isotope, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our future isotopes or bring them to market and generate product revenue.

***We may be dependent on intellectual property licensed or sublicensed to us from, or for which development was funded or otherwise assisted by, government agencies for development of our technology and future isotopes. Failure to meet our own obligations to any licensor or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.***

Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products.

***If we are unable to obtain patent protection for our future isotopes, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.***

We anticipate that we may file patent applications both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when any patents will issue;
- the degree and scope of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose; or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our future isotopes or uses thereof in the United States or in foreign countries.

We currently rely upon a combination of trade secret protection and confidentiality agreements to protect the intellectual property related to our isotope development techniques and future isotopes. Our success will depend in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to the ASP technology and the quantum enrichment technology. We may seek to protect our proprietary position by filing patent applications in the United States and abroad related to its current and future development programs and future isotopes to the extent permitted by applicable law. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our future isotopes in the United States or in foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from being issued from a pending patent application. Even if patents are successfully issued and even if such patents cover the ASP technology and the quantum enrichment technology, third parties may challenge their scope, validity, or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any future isotopes using the ASP technology or the quantum enrichment technology. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a future isotope could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for the ASP technology or the quantum enrichment technology, it could dissuade companies from collaborating with us, and threaten our ability to commercialize, isotopes produced using the ASP technology or the quantum enrichment technology. Any such outcome could have a negative effect on our business.

Even if we obtain patents covering the ASP technology or the quantum enrichment technology or our methods, we may still be barred from making, using and selling such technology or methods because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering technology or methods that are similar or identical to ours, which could materially affect our ability to successfully develop our technology or to successfully commercialize any isotopes alone or with collaborators.

Patent applications in the United States and elsewhere are generally published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our platform technologies and methods could have been filed by others without our knowledge. Additionally, pending claims in patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies. These patent applications may have priority over patent applications filed by us.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We will rely on our outside counsel, patent annuity service providers, or our licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, and other similar provisions during the patent application process. We will employ reputable law firms and other professionals to help us comply. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, and this circumstance could harm our business.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.***

Our commercial success depends, in part, upon our ability and the ability of our current or future collaborators to develop, manufacture, market and sell our future isotopes and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The technology industry is characterized by extensive and complex litigation regarding patents and other intellectual property rights. Our future isotopes and other proprietary technologies we may develop may infringe existing or future patents owned by third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our future isotopes and technology, including interference proceedings, post-grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our future isotopes. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe on a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our future isotope(s) and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or future isotope. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our future isotopes or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our future isotopes or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our future isotopes, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.***

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other technology companies, including Klydon. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

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

If we rely on third parties to manufacture or commercialize our future isotopes, or if we collaborate with additional third parties for the development of our future isotopes, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. A competitor's discovery of our trade secrets could harm our business.

***Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.***

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our future isotopes, technology and product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our future isotopes, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

**Risks Related to Our Dependence on Third Parties**

***If we use hazardous and chemical materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials. We are subject to international and local laws and regulations in South Africa governing the use, manufacture, storage, handling and disposal of radioactive and hazardous materials. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from radioactive or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition, or results of operations.

## **Risks Related to Our Business Operations, Employee Matters and Managing Growth**

***We are highly dependent on the services of our senior management team, and if we are not able to retain these members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed.***

We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

In addition, we will need to attract, retain and motivate highly qualified additional management and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can develop future isotopes and our business will be limited, and we may experience constraints on our development objectives.

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

***We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

As of September 30, 2023, we employed approximately 46 people on a full-time basis, 41 of whom are located in South Africa. We rely on service providers for certain general administrative, financial, accounting, tax, intellectual property and other legal services, and we will need to expand our organization to hire qualified personnel to perform these functions internally. Our management may need to divert significant attention and time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our future isotopes. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance, our ability to commercialize future isotopes, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

We are exposed to the risk of fraud or other misconduct by our employees, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a negative impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

***We and our contractors are highly dependent on the performance of sub-contractors and other third parties.***

We and our contractors are highly dependent on the performance of sub-contractors and other third parties. If these contractors, sub-contractors and third parties are unable to deliver the results that we require, our operating results could be adversely affected and our business could be materially harmed.

***Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.***

We are dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. In addition, some of our employees work remotely, which may make us more vulnerable to cyberattacks. Potential vulnerabilities can be exploited by inadvertent or intentional actions of our employees, third-party vendors, business partners, or malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors’ and/or our business partners’ information technology systems or other similar data security incidents could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation.



There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and/or state breach notification laws and foreign law equivalents, subject us to time-consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us and significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

***Our international operations subject us to risks of doing business in foreign countries, which could adversely affect our business, financial condition and results of operations.***

Our primary operations are located outside the U.S. (primarily the construction of isotope enrichment plants in South Africa), and we plan to sell our isotopes to customers outside the U.S. Accordingly, our business is subject to risks related to the differing legal, political, social and regulatory requirements and economic conditions of non-U.S. jurisdictions. Risks inherent in international operations include the following:

- fluctuations in foreign currency exchange rates may affect product demand and may adversely affect the profitability in U.S. dollars of products and services we provide in international markets where payment for our products and services is made in the local currency;
- transportation and other shipping costs may increase, or transportation may be inhibited;
- increased cost or decreased availability of raw materials;
- changes in foreign laws and tax rates or U.S. laws and tax rates with respect to foreign income may unexpectedly increase the rate at which our income is taxed, impose new and additional taxes on remittances, repatriation or other payments by subsidiaries, or cause the loss of previously recorded tax benefits;
- foreign countries in which we do business may adopt other restrictions on foreign trade or investment, including currency exchange controls;
- trade sanctions by or against these countries could result in our losing access to customers and suppliers in those countries;
- unexpected adverse changes in foreign laws or regulatory requirements may occur;
- our agreements with counterparties in foreign countries may be difficult for us to enforce and related receivables may be difficult for us to collect;
- compliance with the variety of foreign laws and regulations may be unduly burdensome;
- compliance with anti-bribery and anti-corruption laws (such as the Foreign Corrupt Practices Act) as well as anti-money- laundering laws may be costly;
- unexpected adverse changes in export duties, quotas and tariffs and difficulties in obtaining export licenses may occur;
- general economic conditions in the countries in which we operate could have an adverse effect on our earnings from operations in those countries;
- our foreign operations may experience staffing difficulties and labor disputes;
- termination or substantial modification of international trade agreements may adversely affect our access to raw materials and to markets for our products outside the U.S.;
- foreign governments may nationalize or expropriate private enterprises;
- increased sovereign risk (such as default by or deterioration in the economies and creditworthiness of local governments) may occur; and
- political or economic repercussions from terrorist activities, including the possibility of hyperinflationary conditions and political instability, may occur in certain countries in which we do business.

Unanticipated events, such as geopolitical changes, could result in a write-down of our investment in the affected joint venture or a delay or cause cancellation of those capital projects, which could negatively impact our future growth and profitability. Our success as a global business will depend, in part, upon our ability to succeed in differing legal, regulatory, economic, social and political conditions by developing, implementing and maintaining policies and strategies that are effective in each location where we and our joint ventures do business.

Furthermore, we will be subject to rules and regulations related to anti-bribery and anti-trust prohibitions of the U.S. and other countries, as well as export controls and economic embargoes, violations of which may carry substantial penalties. For example, export control and economic embargo regulations limit the ability of our subsidiaries to market, sell, distribute or otherwise transfer their products or technology to prohibited countries or persons. Failure to comply with these regulations could subject our subsidiaries to fines, enforcement actions and/or have an adverse effect on our reputation and the value of our Common Stock.

***Our tangible assets may be subject to defects in title.***

We have investigated our rights to the assets we have purchased and developed, and, to the best of our knowledge, those rights are in good standing. However, no assurance can be given that such rights will not be revoked, or significantly altered, to our detriment. There can also be no assurance that our rights will not be challenged or impugned by third parties, including by governments and non-governmental organizations.

***We are subject to foreign currency risks.***

Our operations are subject to foreign currency fluctuations. Our operating expenses and revenues are primarily transacted in U.S. dollars, while some of our cash balances and expenses are measured in other currencies. Any strengthening or weakening of the U.S. dollar in relation to the currencies of other countries or vice versa can have a material impact on our cash flows and profitability and affect the value of our assets and shareholders' equity.

**Risks Related to Ownership of Our Common Stock**

***We do not know whether an active, liquid and orderly trading market will develop for our Common Stock or what the market price of our Common Stock will be, and as a result, it may be difficult for you to sell your shares of our Common Stock.***

Prior to our IPO in November of 2022, there was no public market for shares of our Common Stock. Although our Common Stock is listed on the Nasdaq Capital Market (Nasdaq), an active trading market for our shares may never develop or be sustained following our IPO. You may not be able to sell your shares quickly or at the market price if trading in shares of our Common Stock is not active. The initial public offering price for our Common Stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our Common Stock after the IPO. As a result of these and other factors, you may be unable to resell your shares of our Common Stock at or above the initial public offering price.

Further, an inactive market may also impair our ability to raise capital by selling shares of our Common Stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of Common Stock as consideration.

***The price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our Common Stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Form 10-Q, these factors include: adverse results or delays in our development activities;

- adverse regulatory decisions, including failure to receive regulatory approval for our future isotopes;
- changes in laws or regulations applicable to our future isotopes, including but not limited to requirements for approvals;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- our inability to obtain adequate product supply for any future isotope or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our future isotopes;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our future isotopes;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- issuances of debt or equity securities;
- sales of our Common Stock by us or our stockholders in the future or the perception that such sales may occur;
- trading volume of our Common Stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions, including the COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Stock, regardless of our actual operating performance, and you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

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

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

Our executive officers, current directors, greater than 5% holders, and their affiliates beneficially own, in the aggregate, approximately 47.5% of our Common Stock as of November 6, 2023. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Common Stock that you may feel are in your best interest as one of our stockholders.

***Sales of a substantial number of shares of our Common Stock by our existing stockholders in the public market, or the perception that such sales could occur, could cause our stock price to fall.***

As of November 6, 2023, we had a total of 48,773,276 shares of Common Stock outstanding, of which approximately 16,840,966 shares were restricted and 31,932,310 were unrestricted.

Subject to the restrictions described in the paragraph below, future sales in the public market of shares will be subject to the volume and other restrictions of Rule 144 under the Securities Act if held by a person that is deemed to be our affiliate, unless the shares to be sold are registered with the SEC. The sale of a substantial number of shares pursuant to Rule 144 or other exemption from registration under the Securities Act, or a perception that such sales could occur, could significantly reduce the market price of our Common Stock.

Of our outstanding Common Stock, the shares held by directors, executive officers, and other affiliates are subject to volume limitations under Rule 144 under the Securities Act. In addition, 3,302,939 shares of Common Stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. Further, 3,386,076 shares of Common Stock are issuable upon the exercise of warrants issued pursuant to a private placement that closed on March 17, 2023. If these additional shares of Common Stock are sold, or if it is perceived that they will be sold in the public market, the trading price of our Common Stock could decline. Any sales of securities by our stockholders could have a material adverse effect on the trading price of our Common Stock.

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

We expect that we will need significant additional capital in the future to continue our planned operations, including development activities, commercialization efforts, if we are able to obtain marketing approval of future isotopes, research and development activities, and costs associated with operating a public company. To raise capital, we may sell Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner that we determine from time to time. If we sell Common Stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our Common Stock.

Pursuant to our 2022 Plan, our management is authorized to grant stock options to our employees, directors and consultants. Additionally, the number of shares of our Common Stock reserved for issuance under our 2022 Plan will automatically increase on January 1 of each year, beginning on January 1, 2023 and continuing through and including January 1, 2032, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year (determined on an as-converted to voting Common Stock basis, without regard to any limitations on the conversion of the non-voting Common Stock), or a lesser number of shares determined by our board of directors. Such issuances will result in dilution to our stockholders.

***We have broad discretion in the use of our existing cash and cash equivalents and may not use them effectively.***

Our management has broad discretion in the application of our existing cash and cash equivalents. Because of the number and variability of factors that will determine our use of our existing cash and cash equivalents, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash and cash equivalents in ways that ultimately increase the value of our Common Stock. The failure by our management to apply these funds effectively could harm our business. We intend to invest our existing cash and cash equivalents that are not used as described above in short- and medium-term, investment-grade, interest-bearing instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our existing cash and cash equivalents in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

***We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our Common Stock less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until December 31, 2027, although circumstances could cause us to lose that status earlier, including if we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act or if we have total annual gross revenue of \$1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company”, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Investors may find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

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 \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting Common Stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

***Delaware law and provisions certificate of incorporation and bylaws, as amended, could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our Common Stock.***

Provisions of certificate of incorporation and bylaws as amended may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our Common Stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that our board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally in the election of directors, voting together as a single class;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder’s notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of Common Stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chair of our board of directors, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under state, statutory and common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (v) any action governed by the internal affairs doctrine, in all cases subject to the court’s having personal jurisdiction over the indispensable parties named as defendants; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction; and provided that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (Securities Act), including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional or entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

These provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding Common Stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our certificate of incorporation and bylaws, as amended and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our Common Stock and limit opportunities for you to realize value in a corporate transaction.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.***

Our amended and restated certificate of incorporation provides that, subject to the court's having personal jurisdiction over the indispensable parties named as defendants, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or bylaws;
- any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any action asserting a claim that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

*We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on the Nasdaq, or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our shareholders to sell their securities.*

Although our Common Stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our Common Stock does not develop or is sustained, our Common Stock may remain thinly traded.

The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders:

- the liquidity of our Common Stock;
- the market price of our Common Stock;
- our ability to obtain financing for the continuation of our operations;
- the number of investors that will consider investing in our Common Stock;
- the number of market makers in our Common Stock;
- the availability of information concerning the trading prices and volume of our Common Stock; and
- the number of broker-dealers willing to execute trades in shares of our Common Stock.

#### **General Risk Factors**

*We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.*

We became a public company in November of 2022, and as a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.



***We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience material weaknesses in the future or otherwise fail to implement and maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations which may adversely affect investor confidence in us, and as a result, the value of our Common Stock.***

Our Common Stock was only recently listed on the Nasdaq Stock Exchange on November 10, 2022. Prior to listing, we were a privately-held company, and as such, we were not required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404(a) of the Sarbanes-Oxley Act, or Section 404. As a public company, we are subject to significant requirements for enhanced financial reporting and internal controls. The process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. In addition, we are required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in the second annual report. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. Testing and maintaining internal controls may divert management's attention from other matters that are important to our business. Once we are no longer an "emerging growth company" or a "smaller reporting company", our auditors will be required to issue an attestation report on the effectiveness of our internal controls on an annual basis.

In the course of preparing the financial statements that are included in this prospectus, management has determined that a material weakness exists within the internal controls over financial reporting. The material weakness identified relates to the lack of a sufficient complement of personnel within the finance and accounting function with an appropriate degree of knowledge, experience and training. We also noted a material weakness related to logical security and privileged access in the area of information technology. We concluded that the material weaknesses in our internal control over financial reporting information technology occurred because, prior to our IPO, we were a private company and did not have the necessary business processes, systems, personnel, and related internal controls necessary to satisfy the accounting and financial reporting requirements of a public company.

In order to remediate the material weaknesses, we expect to hire additional accounting, finance and information technology resources or consultants with public company experience.

We may not be able to fully remediate the identified material weakness until the steps described above have been completed and our internal controls have been operating effectively for a sufficient period of time. We believe we have already and will continue to make progress in our remediation plan but cannot assure you that we will be able to fully remediate the material weakness by such time. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis. We also may incur significant costs to execute various aspects of our remediation plan but cannot provide a reasonable estimate of such costs at this time.

In accordance with the provisions of the JOBS Act, we and our independent registered public accounting firm were not required to, and did not, perform an evaluation of our internal control over financial reporting as of December 31, 2022 nor any period subsequent in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required under Section 404 of the Sarbanes-Oxley Act.

In the future, it is possible that additional material weaknesses or significant deficiencies may be identified that we may be unable to remedy before the requisite deadline for these reports. Our ability to comply with the annual internal control reporting requirements will depend on the effectiveness of our financial reporting and data systems and controls across our company. Any weaknesses or deficiencies or any failure to implement new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, or result in material misstatements in our consolidated financial statements, which could adversely affect our business and reduce our stock price.

If we are unable to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404, our independent registered public accounting firm may not issue an unqualified opinion. If we are unable to conclude that we have effective internal control over financial reporting, investors could lose confidence in our reported financial information, which could have a material adverse effect on the trading price of our Common Stock. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our Common Stock.***

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our Common Stock. On May 5, 2023, we received a letter (the "Nasdaq Staff Deficiency Letter") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last 30 consecutive business days, the closing bid price for our common stock has been below the minimum \$1.00 per share required for continued listing on The Nasdaq Capital (the "Minimum Bid Price Requirement"). In accordance with Nasdaq rules, the Company was provided until November 1, 2023, to regain compliance with the Minimum Bid Price Requirement. On August 11, 2023, the Company received notice from Nasdaq stating that the Company has regained compliance with the Minimum Bid Price Requirement. However, any future failure to satisfy the continued listing requirements of Nasdaq, which results in a delisting, would likely have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

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

The trading market for our Common Stock depends in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

**Use of proceeds from registered securities**

On November 15, 2022, we completed our IPO, in which we issued and sold 1,250,000 shares of Common Stock, \$0.01 par value per share, at a price to the public of \$4.00 per share. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-267392), which was filed with the SEC on September 12, 2022 and amended subsequently and declared effective on November 9, 2022. The underwriter of the IPO was Revere Securities LLC. The Form S-1 registered 2,057,500 shares of Common Stock held by selling stockholders. We did not receive proceeds from the sale of the shares by the selling stockholders.

We raised approximately \$3.8 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses of \$1.2 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Through September 30, 2023, we have used all of the net proceeds from our IPO for matters described in our final IPO prospectus filed with the SEC on November 14, 2022, or our IPO prospectus.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">31.1*</a>	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">31.2*</a>	<a href="#">Certification of Principal Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">32.1*</a>	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
<a href="#">32.2*</a>	<a href="#">Certification of Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because 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 (embedded within the Inline XBRL document)

\* Filed herewith.











