

## Submission Data File

General Information	
Form Type*	10-Q
Contact Name	M2 Compliance
Contact Phone	754-243-5120
Filer Accelerated Status*	Non-Accelerated Filer
Filer File Number	
Filer CIK*	0001449349
Filer CCC*	*****
Filer is Shell Company*	N
Filer is Smaller Reporting Company	Yes
Confirming Copy	No
Notify via Website only	No
Return Copy	Yes
SROS*	NONE
Period*	06-30-2023
Emerging Growth Company	No
Elected not to use extended transition period	No
(End General Information)	

Document Information	
File Count*	4
Document Name 1*	form10-q.htm
Document Type 1*	10-Q
Document Description 1	
Document Name 2*	ex31-1.htm
Document Type 2*	EX-31.1
Document Description 2	
Document Name 3*	ex31-2.htm
Document Type 3*	EX-31.2
Document Description 3	
Document Name 4*	ex32-1.htm
Document Type 4*	EX-32.1
Document Description 4	
(End Document Information)	

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**Form 10-Q**

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: June 30, 2023

OR

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 000-53497

**VIVOS INC**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**80-0138937**

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

**719 Jadwin Avenue,  
Richland, WA 99352**

(Address of principal executive offices, Zip Code)

**(509) 222-9268**

(Registrant's telephone number, including area code)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

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 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, or a smaller reporting 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. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the company 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

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

<b>Title of Each Class</b>	<b>Trading Symbol</b>	<b>Name of Each Exchange on which registered</b>
----------------------------	-----------------------	--

As of August 4, 2023, there were 370,541,528 shares of the registrant's common stock outstanding, 2,071,007 shares of the registrant's Series A Convertible Preferred Stock outstanding, 200,363 of the registrant's Series B Convertible Preferred Stock outstanding and 385,302 of the registrant's Series C Convertible Preferred Stock outstanding.

---

---

---

## TABLE OF CONTENTS

	<u>Page</u>
<b><u>PART I – FINANCIAL INFORMATION</u></b>	
Item 1. <u>Condensed Financial Statements</u>	1
<u>Condensed Balance Sheets as of June 30, 2023 (unaudited) and December 31, 2022</u>	1
<u>Condensed Statements of Operations for the Six and Three Months ended June 30, 2023 and 2022 (unaudited)</u>	2
<u>Condensed Statement of Changes in Stockholders' Equity for the Six Months Ended June 30, 2023 and 2022 (unaudited)</u>	3
<u>Condensed Statements of Cash Flow for the Six Months ended June 30, 2023 and 2022 (unaudited)</u>	4
<u>Notes to Condensed Financial Statements (unaudited)</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	34
Item 4. <u>Controls and Procedures</u>	34
<b><u>PART II – OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	35
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	35
Item 6. <u>Exhibits</u>	35
<b><u>SIGNATURES</u></b>	36

## PART I – FINANCIAL INFORMATION

**VIVOS INC**  
**CONDENSED BALANCE SHEETS**  
**JUNE 30, 2023 (UNAUDITED) AND DECEMBER 31, 2022**

	<u>JUNE 30,</u> <u>2023</u>	<u>DECEMBER 31,</u> <u>2022</u>
	<u>(UNAUDITED)</u>	
<b><u>ASSETS</u></b>		
Current Assets:		
Cash	\$ 1,748,767	\$ 1,706,065
Accounts receivable	6,000	11,000
Prepaid expenses	34,883	25,671
	<u>1,789,650</u>	<u>1,742,736</u>
<b>Total Current Assets</b>	<u>1,789,650</u>	<u>1,742,736</u>
<b>TOTAL ASSETS</b>	<u>\$ 1,789,650</u>	<u>\$ 1,742,736</u>
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
<b>LIABILITIES</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 112,810	\$ 81,692
	<u>112,810</u>	<u>81,692</u>
<b>Total Current Liabilities</b>	<u>112,810</u>	<u>81,692</u>
<b>Total Liabilities</b>	<u>112,810</u>	<u>81,692</u>
Commitments and contingencies	-	-
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, par value, \$0.001, 20,000,000 shares authorized, Series A Convertible Preferred, 5,000,000 shares authorized, 2,071,007 shares issued and outstanding, respectively	2,071	2,071
Additional paid in capital - Series A Convertible preferred stock	8,842,458	8,842,458
Series B Convertible Preferred, 5,000,000 shares authorized, 200,363 shares issued and outstanding, respectively	200	200
Additional paid in capital - Series B Convertible preferred stock	290,956	290,956
Series C Convertible Preferred, 5,000,000 shares authorized, 385,302 shares issued and outstanding, respectively	385	385
Additional paid in capital - Series C Convertible preferred stock	500,507	500,507
Common stock, par value, \$0.001, 950,000,000 shares authorized, 370,541,528 and 362,541,528 issued and outstanding, respectively	370,541	362,541
Additional paid in capital - common stock	72,376,594	71,217,954
Accumulated deficit	(80,706,872)	(79,556,028)
	<u>1,676,840</u>	<u>1,661,044</u>
<b>Total Stockholders' Equity</b>	<u>1,676,840</u>	<u>1,661,044</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 1,789,650</u>	<u>\$ 1,742,736</u>

**VIVOS INC**  
**CONDENSED STATEMENTS OF OPERATIONS (UNAUDITED)**  
**FOR THE SIX AND THREE MONTHS ENDED JUNE 30, 2023 AND 2022**

	<b>SIX MONTHS ENDED</b>		<b>THREE MONTHS ENDED</b>	
	<b>JUNE 30,</b>	<b>JUNE 30,</b>	<b>JUNE 30,</b>	<b>JUNE 30,</b>
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
<b>Revenues, net</b>	\$ 12,500	\$ 23,500	\$ 6,500	\$ 10,500
<b>Cost of Goods Sold</b>	(16,536)	(5,018)	(9,000)	(2,018)
<b>Gross (loss) profit</b>	(4,036)	18,482	(2,500)	8,482
<b>OPERATING EXPENSES</b>				
Professional fees, including stock-based compensation	692,963	1,098,507	608,747	521,470
Payroll expenses	144,521	140,656	72,013	69,869
Research and development	219,728	241,301	173,353	169,732
General and administrative expenses	101,475	73,049	57,792	34,949
<b>Total Operating Expenses</b>	<b>1,158,687</b>	<b>1,553,513</b>	<b>911,905</b>	<b>796,020</b>
<b>OPERATING LOSS</b>	<b>(1,162,723)</b>	<b>(1,535,031)</b>	<b>(914,405)</b>	<b>(787,538)</b>
<b>NON-OPERATING INCOME (EXPENSE)</b>				
Interest income	11,879	-	11,879	-
Gain on debt extinguishment	-	47,588	-	-
<b>Total Non-Operating Income (Expenses)</b>	<b>11,879</b>	<b>47,588</b>	<b>11,879</b>	<b>-</b>
<b>NET LOSS BEFORE PROVISION FOR INCOME TAXES</b>	<b>(1,150,844)</b>	<b>(1,487,443)</b>	<b>(902,526)</b>	<b>(787,538)</b>
Provision for income taxes	-	-	-	-
<b>NET LOSS</b>	<b>\$ (1,150,844)</b>	<b>\$ (1,487,443)</b>	<b>\$ (902,526)</b>	<b>\$ (787,538)</b>
<b>Net loss per share - basic and diluted</b>	<b>\$ (0.00)</b>	<b>\$ (0.00)</b>	<b>\$ (0.00)</b>	<b>\$ (0.00)</b>
<b>Weighted average common shares outstanding</b>	<b>365,370,257</b>	<b>343,761,071</b>	<b>368,167,902</b>	<b>343,906,505</b>

**VIVOS INC**  
**CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (UNAUDITED)**  
**FOR THE SIX MONTHS ENDED JUNE 30, 2023 AND 2022**

	Series A Preferred		Additional Paid-In Capital - Series A Preferred		Series B Preferred		Additional Paid-In Capital - Series B Preferred		Series C Preferred		Additional Paid-In Capital - Series C Preferred		Common Stock		Additional Paid-In Capital - Common		Accumulated Deficit		Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Common	Deficit			
Balance - December 31, 2021	2,071,007	\$ 2,071	8,842,458	200,363	200	290,956	385,302	385	500,507	343,530,678	\$343,531	\$68,573,142					\$(77,085,867)	\$1,467,383	
Stock issued for:																			
Services	-	-	-	-	-	-	-	-	-	76,250	76	4,804	-	-	-	-	-	4,880	
Warrant exercises	-	-	-	-	-	-	-	-	-	299,577	300	(300)	-	-	-	-	-	-	
RSUs granted to consultants that have vested	-	-	-	-	-	-	-	-	-	-	-	450,000	-	-	-	-	-	450,000	
Net loss for the period	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	\$(699,905)	\$(699,905)	
Balance - March 31, 2022	2,071,007	2,071	8,842,458	200,363	200	290,956	385,302	385	500,507	343,906,505	343,907	69,027,646					\$(77,785,772)	1,222,358	
RSUs granted to consultants that have vested	-	-	-	-	-	-	-	-	-	-	-	458,200	-	-	-	-	-	458,200	
Net loss for the period	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	\$(787,538)	\$(787,538)	
Balance - June 30, 2022	2,071,007	\$ 2,071	8,842,458	200,363	\$ 200	290,956	385,302	\$ 385	500,507	343,906,505	\$343,907	\$69,485,846					\$(78,573,310)	\$ 893,020	
Balance - December 31, 2022	2,071,007	\$ 2,071	8,842,458	200,363	\$ 200	290,956	385,302	\$ 385	500,507	362,541,528	\$362,541	\$71,217,954					\$(79,556,028)	\$1,661,044	
Net loss for the period	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	\$(248,318)	\$(248,318)	
Balance - March 31, 2023	2,071,007	2,071	8,842,458	200,363	200	290,956	385,302	385	500,507	362,541,528	362,541	71,217,954					\$(79,804,346)	1,412,726	
Stock issued for:																			
Cash	-	-	-	-	-	-	-	-	-	8,000,000	8,000	632,000	-	-	-	-	-	640,000	
Warrants purchased for cash	-	-	-	-	-	-	-	-	-	-	-	10,665	-	-	-	-	-	10,665	
RSUs granted to consultants that have vested	-	-	-	-	-	-	-	-	-	-	-	515,975	-	-	-	-	-	515,975	
Net loss for the period	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	\$(902,526)	\$(902,526)	
Balance - June 30, 2023	2,071,007	\$ 2,071	8,842,458	200,363	\$ 200	290,956	385,302	\$ 385	500,507	370,541,528	\$370,541	\$72,376,594					\$(80,706,872)	\$1,676,840	

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

**VIVOS INC**  
**CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)**  
**FOR THE SIX MONTHS ENDED JUNE 30, 2023 AND 2022**

	<b>2023</b>	<b>2022</b>
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (1,150,844)	\$ (1,487,443)
Adjustments to reconcile net loss to net cash used in operating activities		
Common stock, stock options and warrants for services	-	4,880
RSUs issued for services	515,975	908,200
(Gain) on conversion of debt	-	(47,588)
<b>Changes in assets and liabilities</b>		
Accounts receivable	5,000	(6,500)
Prepaid expenses and other assets	(9,212)	(22,732)
Accounts payable and accrued expenses	31,118	95,766
Total adjustments	<u>542,881</u>	<u>932,026</u>
<b>Net cash used in operating activities</b>	<u>(607,963)</u>	<u>(555,417)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from common stock and warrants	650,665	-
<b>Net cash provided by financing activities</b>	<u>650,665</u>	<u>-</u>
<b>NET DECREASE IN CASH</b>	42,702	(555,417)
<b>CASH - BEGINNING OF PERIOD</b>	<u>1,706,065</u>	<u>1,606,123</u>
<b>CASH - END OF PERIOD</b>	<u>\$ 1,748,767</u>	<u>\$ 1,050,706</u>
<b>CASH PAID DURING THE PERIOD FOR:</b>		
Interest expense	<u>\$ -</u>	<u>\$ -</u>
Income taxes	<u>\$ -</u>	<u>\$ -</u>
<b>SUPPLEMENTAL INFORMATION - NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Common stock issued in cashless exercise of warrants	<u>\$ -</u>	<u>\$ 300</u>

**Vivos Inc.**  
**Notes to Condensed Financial Statements**  
**(Unaudited)**

**NOTE 1: BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES**

The accompanying condensed financial statements of Vivos Inc. (the “*Company*”) have been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and disclosures required by accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. These condensed financial statements reflect all adjustments that, in the opinion of management, are necessary to present fairly the results of operations of the Company for the period presented. The results of operations for the six and three months ended June 30, 2023, are not necessarily indicative of the results that may be expected for any future period or the fiscal year ending December 31, 2023 and should be read in conjunction with the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 1, 2023.

**Business Overview**

The Company was incorporated under the laws of Delaware on December 23, 1994 as Savage Mountain Sports Corporation (“*SMSC*”). On September 6, 2006, the Company changed its name to Advanced Medical Isotope Corporation, and on December 28, 2017, the Company began operating as Vivos Inc. The Company has authorized capital of 950,000,000 shares of common stock, \$0.001 par value per share, and 20,000,000 shares of preferred stock, \$0.001 par value per share.

Our principal place of business is located at 719 Jadwin Avenue, Richland, WA 99352. Our telephone number is (509) 736-4000. Our corporate website address is <http://www.radiogel.com>. Our common stock is currently quoted on the OTC Pink Marketplace under the symbol “RDGL.”

The Company is a radiation oncology medical device company engaged in the development of its yttrium-90 based brachytherapy device, RadioGel™, for the treatment of non-resectable tumors. A prominent team of radiochemists, scientists and engineers, collaborating with strategic partners, including national laboratories, universities and private corporations, lead the Company’s development efforts. The Company’s overall vision is to globally empower physicians, medical researchers and patients by providing them with new isotope technologies that offer safe and effective treatments for cancer.

In January 2018, the Center for Veterinary Medicine Product Classification Group ruled that RadioGel™ should be classified as a device for animal therapy of feline sarcomas and canine soft tissue sarcomas. Additionally, after a legal review, the Company believes that the device classification obtained from the Food and Drug Administration (“*FDA*”) Center for Veterinary Medicine is not limited to canine and feline sarcomas, but rather may be extended to a much broader population of veterinary cancers, including all or most solid tumors in animals. We expect the result of such classification and label review will be that no additional regulatory approvals are necessary for the use of IsoPet® for the treatment of solid tumors in animals. The FDA does not have premarket authority over devices with a veterinary classification, and the manufacturers are responsible for assuring that the product is safe, effective, properly labeled, and otherwise in compliance with all applicable laws and regulations.

Based on the FDA’s recommendation, RadioGel™ will be marketed as “IsoPet®” for use by veterinarians to avoid any confusion between animal and human therapy. The Company already has trademark protection for the “IsoPet®” name. IsoPet® and RadioGel™ are used synonymously throughout this document. The only distinction between IsoPet® and RadioGel™ is the FDA’s recommendation that we use “IsoPet®” for veterinarian usage, and reserve “RadioGel™” for human therapy. Based on these developments, the Company has shifted its primary focus to the development and marketing of IsoPet® for animal therapy, through the Company’s IsoPet® Solutions division.

**IsoPet Solutions**

The Company’s IsoPet Solutions division was established in May 2016 to focus on the veterinary oncology market, namely engagement of university veterinarian hospital to develop the detailed therapy procedures to treat animal tumors and ultimately use of the technology in private clinics. The Company has worked with three different university veterinarian hospitals on IsoPet® testing and therapy. Washington State University treated five cats for feline sarcoma and served to develop the procedures which are incorporated in our label. They concluded that the product was safe and effective in killing cancer cells. Colorado State University demonstrated the CT and PET-CT imaging of IsoPet®. A contract was signed with University of Missouri to treat canine sarcomas and equine sarcoids starting in November 2017.

The dogs were treated for canine soft tissue sarcoma. Response evaluation criteria in solid tumors (“*RECIST*”) is a set of published rules that define when tumors in cancer patients improve (respond), stay the same (stabilize), or worsen (progress) during treatment. The criteria were published by an international collaboration including the European Organisation for Research and Treatment of Cancer (“*EORTC*”), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group.

The testing at the University of Missouri met its objective to demonstrate the safety of IsoPet<sup>®</sup>. Using its advanced CT and PET equipment it was able to demonstrate that the dose calculations were accurate and that the injections perfused into the cell interstices and did not stay concentrated in a bolus. This results in a more homogeneous dose distribution. There was insignificant spread of Y-90 outside the points of injection demonstrating the effectiveness of the particles and the gel to localize the radiation with no spreading to the blood or other organs nor to urine or fecal material. This confirms that IsoPet<sup>®</sup> is safe for same day therapy.

The effectiveness of IsoPet<sup>®</sup> for life extension was not the prime objective, but it resulted in valuable insights. Of the cases one is still cancer-free but the others eventually recurred since there was not a strong focus on treating the margins. The University of Missouri has agreed to become a regional center to administer IsoPet<sup>®</sup> therapy and will incorporate the improvements suggested by the testing program.

The Company anticipates that future profits, if any, will be derived from direct sales of RadioGel<sup>™</sup> (under the name IsoPet<sup>®</sup>) and related services, and from licensing to private medical and veterinary clinics in the U.S. and internationally. The Company intends to report the results from the IsoPet<sup>®</sup> Solutions division as a separate operating segment in accordance with GAAP.

Commencing in July 2019, the Company recognized its first commercial sale of IsoPet<sup>®</sup>. A veterinarian from Alaska brought his cat with a re-occurrent spindle cell sarcoma tumor on his face. The cat had previously received external beam therapy, but now the tumor was growing rapidly. He was given a high dose of 400Gy with heavy therapy at the margins. This sale met the revenue recognition requirements under ASC 606 as the performance obligation was satisfied. The Company completed sales for an additional four animals that received the IsoPet<sup>®</sup> during 2019.

Our plan is to incorporate the data assembled from our work with Isopet<sup>®</sup> in animal therapy to support the Company's efforts in the development of our RadioGel<sup>™</sup> device candidate, including obtaining approval from the *FDA* to market and sell RadioGel<sup>™</sup> as a Class II medical device. RadioGel<sup>™</sup> is an injectable particle-gel for brachytherapy radiation treatment of cancerous tumors in people and animals. RadioGel<sup>™</sup> is comprised of a hydrogel, or a substance that is liquid at room temperature and then gels when reaching body temperature after injection into a tumor. In the gel are small, less than two microns, yttrium-90 phosphate particles ("Y-90"). Once injected, these inert particles are locked in place inside the tumor by the gel, delivering a very high local radiation dose. The radiation is beta, consisting of high-speed electrons. These electrons only travel a short distance so the device can deliver high radiation to the tumor with minimal dose to the surrounding tissue. Optimally, patients can go home immediately following treatment without the risk of radiation exposure to family members. Since Y-90 has a half-life of 2.7 days, the radioactivity drops to 5% of its original value after ten days.

The Company modified its Indication for Use from skin cancer to cancerous tissue or solid tumors pathologically associated with locoregional papillary thyroid carcinoma and recurrent papillary thyroid carcinoma having discernable tumors associated with metastatic lymph nodes or extranodal disease in patients who are not surgical candidates or who have declined surgery, or patients who require post-surgical remnant ablation (for example, after prior incomplete radioiodine therapy). Papillary thyroid carcinoma belongs to the general class of head and neck tumors for which tumors are accessible by intraoperative direct needle injection. The Company's Medical Advisory Board felt that demonstrating efficacy in clinical trials was much easier with this new indication.

## **Intellectual Property**

Our original license with Battelle National Laboratory is reached its end of life in 2022. During the past several years, in anticipation of this we have expanded our proprietary knowledge, our trademark and patent protection.

Our RadioGel trademark protection is in 17 countries. We have expanded our trademark protection from RadioGel to now include IsoPet. We obtained the International Certificate of Registration for ISOPET, which is the first step to file in several countries.

The Company received the Patent Cooperation Treaty ("PCT") International Search Report on our patent application (No.1811.191). Seven of our claims were immediately ruled as having novelty, inventive step and industrial applicability. This gives us the basis to extend for many years the patent protection for our proprietary Yttrium-90 phosphate particles utilized in Isopet<sup>®</sup> and Radiogel<sup>™</sup>.

Our patent team filed our particle patent in more than ten patent offices that collectively cover 63 countries throughout the world. We filed a continuation-in-part applications number 1774054 in the USA to expand the claims on our particle patent. The US Patent office recently gave us the Notice of Allowance for our patent to produce our yttrium phosphate microparticles, US Patent Application Serial No: 16-459,466. We also filed an amendment to correct the wording on our claims at make them consistent with the USE claims. Ref: 4207-0005; European Patent Application NO. 20 834 229.5; VIVOS INC; Our Ref: FS/53791.

We filed a hydrogel utility patent in the USA (16309:17/943,311) and internationally (16389:PCT/US22/4374) based on the last eighteen months of development work to optimize our hydrogel component. These include reducing the polymer production time and increasing the output by a factor of three. We have also further reduced the level of trace contaminants to be well below the FDA guidelines.

We filed a provisional patent (Serial Number 63436562) to protect our innovative improvements in our shipping container, our vial shield, our syringe shield, and our Peltier chiller. Our objectives were to reduce shipping costs, decrease radiation exposure, and enhance sterility. These devices will be preferentially used at Mayo Clinics for human clinical studies at and our IsoPet regional treatment centers.

We anticipate that Precision Radionuclide Therapy will become increasingly important in the future and expand to other isotope and other indications for use. Therefore, we filed an alternate particle utility patent (Serial number 18/152,137). Vivos Inc will focus its near-term effort on the Yttrium-90 therapy, which we believe is the best beta emitter; however, we leveraged our hydrogel utility patent to incorporate other promising isotopes and compounds for a range of future applications. This includes gamma and alpha particle emitters.

### **Going Concern**

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As shown in the accompanying financial statements, the Company has suffered recurring losses and used significant cash in support of its operating activities and the Company's cash position is not sufficient to support the Company's operations. Research and development of the Company's brachytherapy product line has been funded with proceeds from the sale of equity and debt securities as well as a series of grants. The Company requires funding of approximately \$2.5 million annually to maintain current operating activities.

The Company completed its reverse stock split which was approved by FINRA and went effective on June 28, 2019.

The Company's stock offering under Regulation A+ was qualified by the Securities and Exchange Commission ("SEC") on June 3, 2020. A second Regulation A+ was qualified by the SEC on September 15, 2021 to raise capital for 50,000,000 shares at a price of \$0.10 for a maximum of \$5,000,000. The Company amended this and was able to raise \$1,200,000 in July 2022 at \$0.08 per share (15,000,000 shares) and sold 20,000,000 warrants for \$20,000. An amended Regulation A+ was filed in October 2022 to raise the remaining \$3,800,000 of the \$5,000,000. In April 2023, \$640,000 was raised in the issuance of 8,000,000 common shares, 2,665,000 Series A warrants and 8,000,000 Series B warrants along with \$10,665 in the sale of the warrants.

The Company's Regulation A+'s raised approximately \$5,200,000 from the sale of shares and is using the proceeds generated as follows:

For the animal therapy market:

- Fund the effort to communicate the benefits of IsoPet® to the veterinary community and the pet parents.
- Conduct additional clinical studies to generate more data for the veterinary community
- Subsidize some IsoPet® therapies, if necessary, to ensure that all viable candidates are treated.
- Assist new regional clinics with their license and certification training.

For the human market:

- Enhance the pedigree of the Quality Management System.
- Complete the previously defined pre-clinical testing and additional testing on an animal model closely aligned with our revised indication for use. Report the results to the FDA in a pre-submission meeting.
- Use the feedback from that meeting to write the IDE (Investigational Device Exemption), which is required to initiate clinical trials.

Research and development of the Company's brachytherapy product line has been funded with proceeds from the sale of equity and debt securities. The Company may require additional funding of approximately \$2.5 million annually to maintain current operating activities. Over the next 12 to 48 months, the Company believes it will cost approximately \$9 million to: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet<sup>®</sup> across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States. The proceeds to be raised from the recent qualified Regulation A+ will be used to continue to fund this development.

The continued deployment of the brachytherapy products and a worldwide regulatory approval effort will require additional resources and personnel. The principal variables in the timing and amount of spending for the brachytherapy products in the next 12 to 24 months will be the FDA's classification of the Company's brachytherapy products as Class II or Class III devices (or otherwise) and any requirements for additional studies which may possibly include clinical studies. Thereafter, the principal variables in the amount of the Company's spending and its financing requirements would be the timing of any approvals and the nature of the Company's arrangements with third parties for manufacturing, sales, distribution and licensing of those products and the products' success in the U.S. and elsewhere. The Company intends to fund its activities through strategic transactions such as licensing and partnership agreements or from proceeds to be raised from the recent qualified Regulation A+.

Following receipt of required regulatory approvals and financing, in the U.S., the Company intends to outsource material aspects of manufacturing, distribution, sales and marketing. Outside of the U.S., the Company intends to pursue licensing arrangements and/or partnerships to facilitate its global commercialization strategy.

In the longer-term, subject to the Company receiving adequate funding, regulatory approval for RadioGel<sup>™</sup> and other brachytherapy products, and thereafter being able to successfully commercialize its brachytherapy products, the Company intends to consider resuming research efforts with respect to other products and technologies intended to help improve the diagnosis and treatment of cancer and other illnesses.

Based on the Company's financial history since inception, the Company's independent registered public accounting firm has expressed substantial doubt as to the Company's ability to continue as a going concern. The Company has limited revenue, nominal cash, and has accumulated deficits since inception. If the Company cannot obtain sufficient additional capital, the Company will be required to delay the implementation of its business strategy and may not be able to continue operations.

The Company has been impacted from the effects of COVID-19. The Company's headquarters are in Northeast Washington however their focus of the animal therapy market has been the Northwestern sector of the United States. The Company continues their marketing to the animal therapy market and attempt to increase the exposure to their product and generate revenue accordingly.

As of June 30, 2023, the Company has \$1,748,767 cash on hand. There are currently commitments to vendors for products and services purchased. To continue the development of the Company's products, the current level of cash may not be enough to cover the fixed and variable obligations of the Company.

There is no guarantee that the Company will be able to raise additional funds or to do so at an advantageous price.

The financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent upon its ability to generate sufficient cash flow to meet its obligations on a timely basis and ultimately to attain profitability. The Company plans to seek additional funding to maintain its operations through debt and equity financing and to improve operating performance through a focus on strategic products and increased efficiencies in business processes and improvements to the cost structure. There is no assurance that the Company will be successful in its efforts to raise additional working capital or achieve profitable operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## **Use of Estimates**

The preparation of financial statements in accordance with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates the Company considers include criteria for stock-based compensation expense, and valuation allowances on deferred tax assets. Actual results could differ from those estimates.

## **Financial Statement Reclassification**

Certain account balances from prior periods have been reclassified in these financial statements so as to conform to current period classifications.

## **Cash Equivalents**

For the purposes of the statement of cash flows, the Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

The Company occasionally maintains cash balances in excess of the FDIC insured limit. The Company does not consider this risk to be material.

## **Fair Value of Financial Instruments**

Fair value of financial instruments requires disclosure of the fair value information, whether or not recognized in the balance sheet, where it is practicable to estimate that value. As of June 30, 2023 and December 31, 2022, the balances reported for cash, prepaid expenses, accounts receivable, accounts payable, and accrued expenses, approximate the fair value because of their short maturities.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Accounting Standards Codification (“ASC”) Topic 820 established a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;

Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The Company measures certain financial instruments including options and warrants issued during the period at fair value on a recurring basis.

## **Patents and Intellectual Property**

While patents are being developed or pending, they are not being amortized. Management has determined that the economic life of the patents to be ten years and amortization, over such 10-year period and on a straight-line basis will begin once the patents have been issued and the Company begins utilization of the patents through production and sales, resulting in revenues.

The Company evaluates the recoverability of intangible assets, including patents and intellectual property on a continual basis. Several factors are used to evaluate intangibles, including, but not limited to, management's plans for future operations, recent operating results and projected and expected undiscounted future cash flows.

There have been no such capitalized costs in the six months ended June 30, 2023 and 2022, respectively. However, a patent was filed on July 1, 2019 (No. 1811.191) filed by Michael Korenko and David Swanberg and assigned to the Company based on the Company's proprietary particle manufacturing process. The timing of this filing was important given the Company's plans to make IsoPet<sup>®</sup> commercially available, which it did on or about July 9, 2019. This additional patent protection will strengthen the Company's competitive position. It is the Company's intention to further extend this patent protection to several key countries within one year, as permitted under international patent laws and treaties.

## **Revenue Recognition**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606). This standard provides a single set of guidelines for revenue recognition to be used across all industries and requires additional disclosures. The updated guidance introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company adopted the updated guidance effective January 1, 2018 using the full retrospective method.

Under ASC 606, in order to recognize revenue, the Company is required to identify an approved contract with commitments to perform respective obligations, identify rights of each party in the transaction regarding goods to be transferred, identify the payment terms for the goods transferred, verify that the contract has commercial substance and verify that collection of substantially all consideration is probable. The adoption of ASC 606 did not have an impact on the Company's operations or cash flows.

The Company recognized revenue as they (i) identified the contracts with each customer; (ii) identified the performance obligation in each contract; (iii) determined the transaction price in each contract; (iv) were able to allocate the transaction price to the performance obligations in the contract; and (v) recognized revenue upon the satisfaction of the performance obligation. Upon the sales of the product to complete the procedures on the animals, the Company recognized revenue as that was considered the performance obligation.

All revenue recognized in the six months ended June 30, 2023 and 2022 relate to consulting income with respect to the IsoPet<sup>®</sup> therapies.

### Loss Per Share

The Company accounts for its loss per common share by replacing primary and fully diluted earnings per share with basic and diluted earnings per share. Basic loss per share is computed by dividing loss available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) for the period, and does not include the impact of any potentially dilutive common stock equivalents since the impact would be anti-dilutive. The computation of diluted earnings per share is similar to basic earnings per share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if potentially dilutive common shares had been issued. For the given periods of loss, of the periods ended in the six months ended June 30, 2023 and 2022, the basic earnings per share equals the diluted earnings per share.

The following represent common stock equivalents that could be dilutive in the future as of June 30, 2023 and December 31, 2022, which include the following:

	June 30, 2023	December 31, 2022
Preferred stock	9,909,570	9,909,570
Restricted stock units	28,262,500	25,362,500
Common stock options	2,252,809	2,252,809
Common stock warrants	25,665,000	26,737,500
Total potential dilutive securities	<u>66,089,879</u>	<u>64,762,379</u>

### Research and Development Costs

Research and developments costs, including salaries, research materials, administrative expenses and contractor fees, are charged to operations as incurred. The cost of equipment used in research and development activities which has alternative uses is capitalized as part of fixed assets and not treated as an expense in the period acquired. Depreciation of capitalized equipment used to perform research and development is classified as research and development expense in the year computed.

The Company incurred \$219,728 and \$241,301 in research and development costs for the six months ended June 30, 2023 and 2022, respectively, all of which were recorded in the Company's operating expenses noted on the statements of operations for the periods then ended.

### Advertising and Marketing Costs

Advertising and marketing costs are expensed as incurred except for the cost of tradeshow which are deferred until the tradeshow occurs. During the six months ended June 30, 2023 and 2022, the Company incurred nominal advertising and marketing costs.

## **Contingencies**

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, and a variety of other matters. The Company records contingent liabilities resulting from asserted and unasserted claims against it, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. The Company discloses contingent liabilities when there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimated probable losses require analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. The Company has entered into various agreements that require them to pay certain fees to consultants and/or employees that have been fully accrued for as of June 30, 2023 and December 31, 2022.

## **Income Taxes**

To address accounting for uncertainty in tax positions, the Company clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position is required to meet before being recognized in the financial statements. The Company also provides guidance on de-recognition, measurement, classification, interest, and penalties, accounting in interim periods, disclosure and transition.

The Company files income tax returns in the U.S. federal jurisdiction. The Company did not have any tax expense for the six months ended June 30, 2023 and 2022. The Company did not have any deferred tax liability or asset on its balance sheets on June 30, 2023 and December 31, 2022.

Interest costs and penalties related to income taxes, if any, will be classified as interest expense and general and administrative costs, respectively, in the Company's financial statements. For the six months ended June 30, 2023 and 2022, the Company did not recognize any interest or penalty expense related to income taxes. The Company believes that it is not reasonably possible for the amounts of unrecognized tax benefits to significantly increase or decrease within the next twelve months.

## **Stock-Based Compensation**

The Company recognizes compensation costs under FASB ASC Topic 718, Compensation – Stock Compensation and ASU 2018-07. Companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share based compensation arrangements include stock options, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. As such, compensation cost is measured on the date of grant at their fair value. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

## **Recent Accounting Pronouncements**

The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

## NOTE 2: RELATED PARTY TRANSACTIONS

### Preferred and Common Shares Issued to Officers and Directors

In March 2022, the Chief Executive Officer exercised 75,000 warrants in a cashless exercise into 22,266 shares of common stock, and was issued 76,250 shares of common stock valued at \$4,880 for services rendered.

## NOTE 3: STOCKHOLDERS' EQUITY

### Common Stock

The Company has 950,000,000 shares of common stock authorized, with a par value of \$0.001, and as of June 30, 2023 and December 31, 2022, the Company has 370,541,528 and 362,541,528 shares issued and outstanding, respectively.

### Preferred Stock

As of June 30, 2023 and December 31, 2022, the Company has 20,000,000 shares of Preferred stock authorized with a par value of \$0.001. The Company's Board of Directors is authorized to provide for the issuance of shares of preferred stock in one or more series, fix or alter the designations, preferences, rights, qualifications, limitations or restrictions of the shares of each series, including the dividend rights, dividend rates, conversion rights, voting rights, term of redemption including sinking fund provisions, redemption price or prices, liquidation preferences and the number of shares constituting any series or designations of such series without further vote or action by the shareholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of management without further action by the shareholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others.

On October 8, 2018 the Company created out of the shares of Preferred Stock, par value \$0.001 per share, of the Company, as authorized in Article IV of the Company's Certificate of Incorporation, a series of Preferred Stock of the Company, to be named "Series B Convertible Preferred Stock," consisting of Five Million (5,000,000) shares.

On March 27, 2019 the Company created out of the shares of Preferred Stock, par value \$0.001 per share, of the Company, as authorized in Article IV of the Company's Certificate of Incorporation, a series of Preferred Stock of the Company, to be named "Series C Convertible Preferred Stock," consisting of Five Million (5,000,000) shares.

#### *Series A Convertible Preferred Stock ("Series A Convertible Preferred")*

In June 2015, the Series A Certificate of Designation was filed with the Delaware Secretary of State to designate 2.5 million shares of our preferred stock as Series A Convertible Preferred. Effective March 31, 2016, the Company amended the Certificate of Designations, Preferences and Rights of Series A Convertible Preferred of the Registrant, increasing the maximum number of shares of Series A Convertible Preferred from 2,500,000 shares to 5,000,000 shares. The following summarizes the current rights and preferences of the Series A Convertible Preferred:

Liquidation Preference. The Series A Convertible Preferred has a liquidation preference of \$5.00 per share.

Dividends. Shares of Series A Convertible Preferred do not have any separate dividend rights.

Conversion. Subject to certain limitations set forth in the Series A Certificate of Designation, each share of Series A Convertible Preferred is convertible, at the option of the holder, into that number of shares of common stock (the "*Series A Conversion Shares*") equal to the liquidation preference thereof, divided by Conversion Price (as such term is defined in the Series A Certificate of Designation), currently \$4.00.

In the event the Company completes an equity or equity-based public offering, registered with the SEC, resulting in gross proceeds to the Company totaling at least \$5.0 million, all issued and outstanding shares of Series A Convertible Preferred at that time will automatically convert into Series A Conversion Shares.

Redemption. Subject to certain conditions set forth in the Series A Certificate of Designation, in the event of a Change of Control (defined in the Series A Certificate of Designation as the time at which as a third party not affiliated with the Company or any holders of the Series A Convertible Preferred shall have acquired, in one or a series of related transactions, equity securities of the Company representing more than fifty percent 50% of the outstanding voting securities of the Company), the Company, at its option, will have the right to redeem all or a portion of the outstanding Series A Convertible Preferred in cash at a price per share of Series A Convertible Preferred equal to 100% of the Liquidation Preference.

Voting Rights. Holders of Series A Convertible Preferred are entitled to vote on all matters, together with the holders of common stock, and have the equivalent of five (5) votes for every Series A Conversion Share issuable upon conversion of such holder's outstanding shares of Series A Convertible Preferred. However, the Series A Conversion Shares, when issued, will have all the same voting rights as other issued and outstanding common stock of the Company, and none of the rights of the Series A Convertible Preferred.

Liquidation. Upon any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary (a "*Liquidation*"), the holders of Series A Convertible Preferred shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount equal to the liquidation preference of the Series A Convertible Preferred before any distribution or payment shall be made to the holders of any junior securities, and if the assets of the Company is insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of the Series A Convertible Preferred shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Certain Price and Share Adjustments.

a) *Stock Dividends and Stock Splits.* If the Company (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents; (ii) subdivides outstanding shares of common stock into a larger number of shares; (iii) combines (including by way of a reverse stock split) outstanding shares of common stock into a smaller number of shares; or (iv) issues, in the event of a reclassification of shares of the common stock, any shares of capital stock of the Company, then the conversion price shall be adjusted accordingly.

b) *Merger or Reorganization.* If the Company is involved in any reorganization, recapitalization, reclassification, consolidation or merger in which the Common Stock is converted into or exchanged for securities, cash or other property than each share of Series A Preferred shall be convertible into the kind and amount of securities, cash or other property that a holder of the number of shares of common stock issuable upon conversion of one share of Series A Convertible Preferred prior to any such merger or reorganization would have been entitled to receive pursuant to such transaction.

*Series B Convertible Preferred Stock ("Series B Convertible Preferred")*

In October 2018, the Series B Certificate of Designation was filed with the Delaware Secretary of State to designate 5.0 million shares of our preferred stock as Series B Convertible Preferred. The following summarizes the current rights and preferences of the Series B Convertible Preferred:

Liquidation Preference. The Series B Convertible Preferred has a liquidation preference of \$1.00 per share.

Dividends. Shares of Series B Convertible Preferred do not have any separate dividend rights.

Conversion. Subject to certain limitations set forth in the Series B Certificate of Designation, each share of Series B Convertible Preferred is convertible, at the option of the holder, into that number of shares of common stock (the "*Series B Conversion Shares*") equal to the liquidation preference thereof, divided by Conversion Price (as such term is defined in the Series B Certificate of Designation), currently \$0.08.

Redemption. Subject to certain conditions set forth in the Series B Certificate of Designation, in the event of a Change of Control (defined in the Series B Certificate of Designation as the time at which as a third party not affiliated with the Company or any holders of the Series B Convertible Preferred shall have acquired, in one or a series of related transactions, equity securities of the Company representing more than fifty percent 50% of the outstanding voting securities of the Company), the Company, at its option, will have the right to redeem all or a portion of the outstanding Series B Convertible Preferred in cash at a price per share of Series B Convertible Preferred equal to 100% of the Liquidation Preference.

Voting Rights. Holders of Series B Convertible Preferred are entitled to vote on all matters, together with the holders of common stock, and have the equivalent of two (2) votes for every Series B Conversion Share issuable upon conversion of such holder's outstanding shares of Series B Convertible Preferred. However, the Series B Conversion Shares, when issued, will have all the same voting rights as other issued and outstanding common stock of the Company, and none of the rights of the Series A Convertible Preferred.

Liquidation. Upon any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary (a "*Liquidation*"), the holders of Series B Convertible Preferred shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount equal to the liquidation preference of the Series B Convertible Preferred before any distribution or payment shall be made to the holders of any junior securities, and if the assets of the Company is insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of the Series B Convertible Preferred shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Certain Price and Share Adjustments.

a) *Stock Dividends and Stock Splits.* If the Company (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents; (ii) subdivides outstanding shares of common stock into a larger number of shares; (iii) combines (including by way of a reverse stock split) outstanding shares of common stock into a smaller number of shares; or (iv) issues, in the event of a reclassification of shares of the common stock, any shares of capital stock of the Company, then the conversion price shall be adjusted accordingly.

b) *Merger or Reorganization.* If the Company is involved in any reorganization, recapitalization, reclassification, consolidation or merger in which the Common Stock is converted into or exchanged for securities, cash or other property than each share of Series B Convertible Preferred shall be convertible into the kind and amount of securities, cash or other property that a holder of the number of shares of common stock issuable upon conversion of one share of Series B Convertible Preferred prior to any such merger or reorganization would have been entitled to receive pursuant to such transaction.

*Series C Convertible Preferred Stock ("Series C Convertible Preferred")*

In March 2019, the Series C Certificate of Designation was filed with the Delaware Secretary of State to designate 5.0 million shares of our preferred stock as Series C Convertible Preferred. The following summarizes the current rights and preferences of the Series C Convertible Preferred:

Liquidation Preference. The Series C Convertible Preferred has a liquidation preference of \$1.00 per share.

Dividends. Shares of Series C Convertible Preferred do not have any separate dividend rights.

Conversion. Subject to certain limitations set forth in the Series C Certificate of Designation, each share of Series C Convertible Preferred is convertible, at the option of the holder, into that number of shares of common stock (the "*Series C Conversion Shares*") equal to the liquidation preference thereof, divided by Conversion Price (as such term is defined in the Series C Certificate of Designation), currently \$0.08.

The Series C Convertible Preferred will only be convertible at any time after the date that the Company shall have amended its Certificate of Incorporation to increase the number of shares of common stock authorized for issuance thereunder or effect a reverse stock split of the outstanding shares of common stock by a sufficient amount to permit the conversion of all Series C Convertible Preferred into shares of common stock (“*Authorized Share Approval*”) (such date, the “*Initial Convertibility Date*”), each share of Series C Convertible Preferred shall be convertible into validly issued, fully paid and non-assessable shares of Common Stock on the terms and conditions set forth in the Series C Certificate of Designation under the definition “*Conversion Rights*”.

**Redemption.** Subject to certain conditions set forth in the Series C Certificate of Designation, in the event of a Change of Control (defined in the Series C Certificate of Designation as the time at which as a third party not affiliated with the Company or any holders of the Series C Convertible Preferred shall have acquired, in one or a series of related transactions, equity securities of the Company representing more than fifty percent 50% of the outstanding voting securities of the Company), the Company, at its option, will have the right to redeem all or a portion of the outstanding Series C Convertible Preferred in cash at a price per share of Series C Convertible Preferred equal to 100% of the Liquidation Preference.

**Voting Rights.** Holders of Series C Convertible Preferred are entitled to vote on all matters, together with the holders of common stock, and have the equivalent of thirty-two (32) votes for every Series C Conversion Share issuable upon conversion of such holder’s outstanding shares of Series C Convertible Preferred. However, the Series C Conversion Shares, when issued, will have all the same voting rights as other issued and outstanding common stock of the Company, and none of the rights of the Series C Convertible Preferred.

**Liquidation.** Upon any liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary (a “*Liquidation*”), the holders of Series C Convertible Preferred shall be entitled to receive out of the assets, whether capital or surplus, of the Company an amount equal to the liquidation preference of the Series C Convertible Preferred before any distribution or payment shall be made to the holders of any junior securities, and if the assets of the Company is insufficient to pay in full such amounts, then the entire assets to be distributed to the holders of the Series C Convertible Preferred shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

#### **Certain Price and Share Adjustments.**

a) *Stock Dividends and Stock Splits.* If the Company (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents; (ii) subdivides outstanding shares of common stock into a larger number of shares; (iii) combines (including by way of a reverse stock split) outstanding shares of common stock into a smaller number of shares; or (iv) issues, in the event of a reclassification of shares of the common stock, any shares of capital stock of the Company, then the conversion price shall be adjusted accordingly.

b) *Merger or Reorganization.* If the Company is involved in any reorganization, recapitalization, reclassification, consolidation or merger in which the Common Stock is converted into or exchanged for securities, cash or other property than each share of Series C Convertible Preferred shall be convertible into the kind and amount of securities, cash or other property that a holder of the number of shares of common stock issuable upon conversion of one share of Series C Convertible Preferred prior to any such merger or reorganization would have been entitled to receive pursuant to such transaction.

#### ***Common and Preferred Stock Issuances – 2023***

In April 2023, the Company issued 8,000,000 shares of common stock, 2,665,000 Series A warrants and 8,000,000 Series B warrants in their Reg A+ for \$640,000. The Company sold the warrants for \$10,665.

#### ***Common and Preferred Stock Issuances - 2022***

In March 2022, the Company issued 299,577 shares of common stock in the cashless exercise of 825,000 warrants, and issued 76,250 shares of common stock to its CEO for services rendered valued at \$4,880. In June 2022, there was a fractional adjustment recorded for 90 shares.

#### NOTE 4: COMMON STOCK OPTIONS, WARRANTS AND RESTRICTED STOCK UNITS

##### Common Stock Options

The Company recognizes in the financial statements compensation related to all stock-based awards, including stock options and warrants, based on their estimated grant-date fair value. The Company has estimated expected forfeitures and is recognizing compensation expense only for those awards expected to vest. All compensation is recognized by the time the award vests.

The following schedule summarizes the changes in the Company's stock options:

	Options Outstanding		Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value	Weighted Average Exercise Price Per Share
	Number Of Shares	Exercise Price Per Share			
Balance at December 31, 2021	2,252,809	\$ 0.024-0.04	7.70 years	\$ 83,992	\$ 0.04
Options granted	-	\$ -	-	-	\$ -
Options exercised	-	\$ -	-	-	\$ -
Options expired/canceled	-	\$ -	-	-	\$ -
Balance at December 31, 2022	<u>2,252,809</u>	<u>\$ 0.024-0.04</u>	<u>6.70 years</u>	<u>\$ 16,032</u>	<u>\$ 0.04</u>
Exercisable at December 31, 2022	<u>2,252,809</u>	<u>\$ 0.024-0.04</u>	<u>6.70 years</u>	<u>\$ 16,032</u>	<u>\$ 0.04</u>
Balance at December 31, 2022	2,252,809	\$ 0.024-0.04	6.70 years	\$ 16,032	\$ 0.04
Options granted	-	\$ -	-	-	\$ -
Options exercised	-	\$ -	-	-	\$ -
Options expired/canceled	-	\$ -	-	-	\$ -
Balance at June 30, 2023	<u>2,252,809</u>	<u>\$ 0.024-0.04</u>	<u>6.20 years</u>	<u>\$ 39,462</u>	<u>\$ 0.04</u>
Exercisable at June 30, 2023	<u>2,252,809</u>	<u>\$ 0.024-0.04</u>	<u>6.20 years</u>	<u>\$ 39,462</u>	<u>\$ 0.04</u>

During the six months ended June 30, 2023 and 2022, the Company recognized \$0 and \$0, respectively, worth of stock based compensation related to the vesting of its stock options.

## Common Stock Warrants

The following schedule summarizes the changes in the Company's stock warrants:

	Warrants Outstanding		Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value	Weighted Average Exercise Price Per Share
	Number Of Shares	Exercise Price Per Share			
Balance at December 31, 2021	31,862,500	\$ 0.04-0.10	1.02 years	\$ 538,875	\$ 0.07
Warrants granted	20,000,000	\$ 0.01 – 0.08	2.50		\$ 0.0725
Warrants exercised	(4,158,333)	\$ -	-		\$ -
Warrants expired/cancelled	(20,966,667)	\$ -	-		\$ -
Balance at December 31, 2022	26,737,500	\$ 0.08-0.10	1.52 years	\$ -	\$ 0.09
Exercisable at December 31, 2022	26,737,500	\$ 0.06-0.10	1.52 years	\$ -	\$ 0.09
Warrants granted	10,665,000	\$ 0.0775	-	-	\$ -
Warrants redeemed	(500,000)	\$ -	-	-	\$ -
Warrants expired/cancelled	(11,237,500)	\$ -	-	-	\$ -
Balance at June 30, 2023	25,665,000	\$ 0.06-0.10	2.16 years	\$ 119,392	\$ 0.079
Exercisable at June 30, 2023	25,665,000	\$ 0.06-0.10	2.16 years	\$ 119,392	\$ 0.079

Changes to these inputs could produce a significantly higher or lower fair value measurement. The fair value of each option/warrant is estimated using the Black-Scholes valuation model. The following assumptions were used for the periods as follows:

	<b>Six Months Ended June 30, 2023</b>	<b>Year Ended December 31, 2022</b>
Expected term	-	.5 – 3 years
Expected volatility	-%	66%
Expected dividend yield	-	-
Risk-free interest rate	-%	3%

In March 2022 the Company issued 299,577 shares of common stock in the cashless exercise of 825,000 warrants.

### Restricted Stock Units

The following schedule summarizes the changes in the Company's restricted stock units:

	<b>Number Of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Balance at December 31, 2021	25,262,500	\$ 0.08
RSU's granted	100,000	\$ 0.082
RSU's vested	(15,100,000)	\$ -
RSU's forfeited	-	\$ -
Balance at December 31, 2022	10,262,500	\$ 0.08
RSUs granted	2,900,000	\$ 0.091
RSUs vested	(5,000,000)	\$ -
Balance at June 30, 2023	<u>8,162,500</u>	<u>\$ 0.09</u>

During the six months ended June 30, 2023 and 2022, the Company recognized \$515,975 and \$908,200 worth of expense related to the vesting of its RSU's. As of June 30, 2023, the Company had \$803,325 worth of expense yet to be recognized for RSU's not yet vested.

On February 3, 2022 and May 3, 2022, 10,000,000 of the RSUs valued at \$900,000 to the CEO vested. On June 1, 2022, 100,000 RSUs were granted to a consultant valued at \$8,200 that were vested immediately.

On May 1, 2023, the Company granted 2,900,000 RSUs to consultants that vest 25% immediately, 25% December 31, 2023, 25% December 31, 2024 and 25% December 31, 2025. These RSUs are valued at \$263,900.

### NOTE 5: COMMITMENT

On June 4, 2019, the Company entered into an Executive Employment Agreement ("Employment Agreement") with Dr. Michael K. Korenko, the Company's Chief Executive Officer. The employment term under the Employment Agreement commenced with an effective date of June 11, 2019 and expires on December 31, 2020, and December 31 of each successive year if the Employment Agreement is extended, unless terminated earlier as set forth in the Employment Agreement. The Company on December 31, 2020 extended this agreement through December 31, 2021 while renegotiating terms of a new Employment Agreement. On May 3, 2021, the Company and the Chief Executive Officer agreed the terms of a new Employment Agreement with an effective date of January 1, 2021 that has a term of three years and expires December 31, 2023.

Under the terms of the Employment Agreement, the Company shall pay to Dr. Korenko a base compensation of \$225,000. In addition, there is a discretionary bonus to be earned in the amount of \$7,500 per quarter upon the satisfaction of conditions to be determined by the Board of Directors of the Company.

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

Except for statements of historical fact, certain information described in this Form 10-Q report contains "forward-looking statements" that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "should," "will," "would" or similar words. The statements that contain these or similar words should be read carefully because these statements discuss the Company's future expectations, including its expectations of its future results of operations or financial position, or state other "forward-looking" information. Vivos Inc. believes that it is important to communicate its future expectations to its investors. However, there may be events in the future that the Company is not able to accurately predict or to control. Further, the Company urges you to be cautious of the forward-looking statements which are contained in this Form 10-Q report because they involve risks, uncertainties and other factors affecting its operations, market growth, service, products and licenses. The risk factors in the section captioned "Risk Factors" in Item 1A of the Company's previously filed Form 10-K, as well as other cautionary language in this Form 10-Q report, describe such risks, uncertainties and events that may cause the Company's actual results and achievements, whether expressed or implied, to differ materially from the expectations the Company describes in its forward-looking statements. The occurrence of any of the events described as risk factors could have a material adverse effect on the Company's business, results of operations and financial position.

Vivos Inc. is a radiation oncology medical device company engaged in the development of its yttrium-90 ("Y-90") based brachytherapy device, RadioGel™, for the treatment of non-resectable tumors. A prominent team of radiochemists, scientists and engineers, collaborating with strategic partners, including national laboratories, universities and private corporations, lead the Company's development efforts. The Company's overall vision is to globally empower physicians, medical researchers and patients by providing them with new isotope technologies that offer safe and effective treatments for cancer.

In 2013 the FDA issued the determination that RadioGel™ is a device for human therapy for non-resectable cancers in humans. This should result in a faster path than a drug for final approval.

In January 2018, the Center for Veterinary Medicine Product Classification Group ruled that RadioGel™ should be classified as a device for animal therapy of feline sarcomas and canine soft tissue sarcomas. Additionally, after a legal review, the Company believes that the device classification obtained from the Food and Drug Administration ("FDA") Center for Veterinary Medicine is not limited to canine and feline sarcomas, but rather may be extended to a much broader population of veterinary cancers, including all or most solid tumors in animals. We expect the result of such classification and label review will be that no additional regulatory approvals are necessary for the use of IsoPet® for the treatment of solid tumors in animals. The FDA does not have premarket authority over devices with a veterinary classification, and the manufacturers are responsible for assuring that the product is safe, effective, properly labeled, and otherwise in compliance with all applicable laws and regulations.

Based on the FDA's recommendation, RadioGel™ will be marketed as "IsoPet®" for use by veterinarians to avoid any confusion between animal and human therapy. The Company already has trademark protection for the "IsoPet®" name. IsoPet® and RadioGel™ are used synonymously throughout this document. The only distinction between IsoPet® and RadioGel™ is the FDA's recommendation that we use "IsoPet®" for veterinarian usage, and reserve "RadioGel™" for human therapy. Based on these developments, the Company has shifted its primary focus to the development and marketing of IsoPet® for animal therapy, through the Company's IsoPet® Solutions division.

The Company's IsoPet Solutions division was established in May 2016 to focus on the veterinary oncology market, namely engagement of university veterinarian hospital to develop the detailed therapy procedures to treat animal tumors and ultimately use of the technology in private clinics. The Company has worked with three different university veterinarian hospitals on IsoPet® testing and therapy. Washington State University treated five cats for feline sarcoma and served to develop the procedures which are incorporated in our label. They concluded that the product was safe and effective in killing cancer cells. Colorado State University demonstrated the CT and PET-CT imaging of IsoPet®. A contract was signed with University of Missouri to treat canine sarcomas and equine sarcoids starting in November 2017.

The dogs were treated for canine soft tissue sarcoma. Response evaluation criteria in solid tumors ("RECIST") is a set of published rules that define when tumors in cancer patients improve (respond), stay the same (stabilize), or worsen (progress) during treatment. The criteria were published by an international collaboration including the European Organisation for Research and Treatment of Cancer ("EORTC"), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group.

The testing at the University of Missouri met its objective to demonstrate the safety of IsoPet®. Using its advanced CT and PET equipment it was able to demonstrate that the dose calculations were accurate and that the injections perfused into the cell interstices and did not stay concentrated in a bolus. This results in a more homogeneous dose distribution. There was insignificant spread of Y-90 outside the points of injection demonstrating the effectiveness of the particles and the gel to localize the radiation with no spreading to the blood or other organs nor to urine or fecal material. This confirms that IsoPet® is safe for same day therapy.

The effectiveness of IsoPet® for life extension was not the prime objective, but it resulted in valuable insights. Of the cases one is still cancer-free but the others eventually recurred since there was not a strong focus on treating the margins. The University of Missouri has agreed to become a regional center to administer IsoPet® therapy and will incorporate the improvements suggested by the testing program.

The Company anticipates that future profits, if any, will be derived from direct sales of RadioGel™ (under the name IsoPet®) and related services, and from licensing to private medical and veterinary clinics in the U.S. and internationally. The Company intends to report the results from the IsoPet® Solutions division as a separate operating segment in accordance with GAAP.

Commencing in July 2019, the Company recognized its first commercial sale of IsoPet®. A veterinarian from Alaska brought his cat with a re-occurrent spindle cell sarcoma tumor on his face. The cat had previously received external beam therapy, but now the tumor was growing rapidly. He was given a high dose of 400Gy with heavy therapy at the margins. This sale met the revenue recognition requirements under ASC 606 as the performance obligation was satisfied. The Company completed sales for an additional four animals that received the IsoPet® during 2019.

Our plan is to incorporate the data assembled from our work with IsoPet® in animal therapy to support the Company's efforts in the development of our RadioGel™ device candidate, including obtaining approval from the FDA to market and sell RadioGel™ as a Class II medical device. RadioGel™ is an injectable particle-gel for brachytherapy radiation treatment of cancerous tumors in people and animals. RadioGel™ is comprised of a hydrogel, or a substance that is liquid at room temperature and then gels when reaching body temperature after injection into a tumor. In the gel are small, less than two microns, Y-90 phosphate particles. Once injected, these inert particles are locked in place inside the tumor by the gel, delivering a very high local radiation dose. The radiation is beta, consisting of high-speed electrons. These electrons only travel a short distance so the device can deliver high radiation to the tumor with minimal dose to the surrounding tissue. Optimally, patients can go home immediately following treatment without the risk of radiation exposure to family members. Since Y-90 has a half-life of 2.7 days, the radioactivity drops to 5% of its original value after ten days.

Recently, the Company modified its Indication for Use from skin cancer to cancerous tissue or solid tumors pathologically associated with locoregional papillary thyroid carcinoma and recurrent papillary thyroid carcinoma having discernable tumors associated with metastatic lymph nodes or extranodal disease in patients who are not surgical candidates or who have declined surgery, or patients who require post-surgical remnant ablation (for example, after prior incomplete radioiodine therapy). Papillary thyroid carcinoma belongs to the general class of head and neck tumors for which tumors are accessible by intraoperative direct needle injection. The Company's Medical Advisory Board felt that demonstrating efficacy in clinical trials was much easier with this new indication.

### **Intellectual Property**

Our original license with Battelle National Laboratory reached its end of life in 2022. During the past several years, in anticipation of this we have expanded our proprietary knowledge, our trademark and patent protection.

Our RadioGel trademark protection is in 17 countries. We have expanded our trademark protection from RadioGel to now include IsoPet. We obtained the International Certificate of Registration for ISOPET, which is the first step to file in several countries.

The Company received the Patent Cooperation Treaty ("PCT") International Search Report on our patent application (No.1811.191). Seven of our claims were immediately ruled as having novelty, inventive step and industrial applicability. This gives us the basis to extend for many years the patent protection for our proprietary Yttrium-90 phosphate particles utilized in Isopet<sup>®</sup> and Radiogel<sup>™</sup>.

Our patent team filed our particle patent in more than ten patent offices that collectively cover 63 countries throughout the world. We filed a continuation-in-part applications number 1774054 in the USA to expand the claims on our particle patent. The US Patent office recently gave us the Notice of Allowance for our patent to produce our yttrium phosphate microparticles, US Patent Application Serial No: 16-459,466. We also filed an amendment to correct the wording on our claims at make them consistent with the USE claims. Ref: 4207-0005; European Patent Application NO. 20 834 229.5; VIVOS INC; Our Ref: FS/53791.

We filed a hydrogel utility patent in the USA (16309:17/943,311) and internationally (16389:PCT/US22/4374) based on the last eighteen months of development work to optimize our hydrogel component. These include reducing the polymer production time and increasing the output by a factor of three. We have also further reduced the level of trace contaminants to be well below the FDA guidelines.

We filed a provisional patent (Serial Number 63436562) to protect our innovative improvements in our shipping container, our vial shield, our syringe shield, and our Peltier chiller. Our objectives were to reduce shipping costs, decrease radiation exposure, and enhance sterility. These devices will be preferentially used at Mayo Clinics for human clinical studies at and our IsoPet regional treatment centers.

We anticipate that Precision Radionuclide Therapy will become increasingly important in the future and expand to other isotope and other indications for use. Therefore, we filed an alternate particle utility patent (Serial number 18/152,137). Vivos Inc will focus its near-term effort on the Yttrium-90 therapy, which we believe is the best beta emitter; however, we leveraged our hydrogel utility patent to incorporate other promising isotopes and compounds for a range of future applications. This includes gamma and alpha particle emitters.

## IsoPet Regional Clinics

We currently have four regional therapy clinics:

- Vista Veterinary Hospital – Kennewick, WA
- University of Missouri – Columbia, MO
- Johns Hopkins University – Baltimore, MD
- New England Equine Practice – Patterson, NY

Vista Veterinary Hospital (“Vista”) was selected as the pilot private clinic to initiate commercial sales of IsoPet<sup>®</sup>. It is good management practice to implement and learn from a pilot program before spreading to regional clinics across the country. Vista is located in the Tri-Cities Washington area which is convenient for interactions with key personnel of the Company. The pilot is being used to

- Refine the Memorandum of Understanding to define all the germane interfaces, roles and liabilities between Vista Inc and the private clinics, including the pilot responsibility to document and share the key aspects of all therapies with the Company;
- Create and implement proprietary certification training packages;
- Amend the production center radioactive material license at IsoTherapeutics, the Company’s IsoPet<sup>®</sup> production center, to allow distribution for commercial applications;
- Work with the pilot program to obtain a radioactive material licensing in an NRC agreement state;
- Create equipment and supplies list;
- Create and post regulatory signage;
- Explore different IsoPet<sup>®</sup> pricing options;
- Evaluate different approaches to obtain patients;
- Optimize patient scheduling practices to reduce cost to the pet owners;
- Develop communication material and a liability document for the pet owners; and
- Further refine the therapy techniques for advanced cancers.

Vista Veterinary Hospital has done well on two audits by the Washington State Department of Health. The Company is working closely with the Washington State Department of Health to refine and improve the radioactive material license. The Company has added several detailed procedures, which will benefit future regional clinics. In addition, a second veterinarian has completed all the preliminary requirements to become certified. All that remains is to demonstrate proficiency in three therapies.

The testing at the universities and at Vista Veterinary Hospital have demonstrated that IsoPet<sup>®</sup> is effective on killing cancer tissue near the injections. It is most effective in early cases before the cancer has begun to spread. Later stage cancers are more difficult to treat since the tendrils from the primary cancer site are not well defined and therefore can lead to recurrence.

There have been 115 expressions of interest in IsoPet<sup>®</sup> therapy from across the United States, but only about 10% of these were treated and they were very advanced cases. The reasons are instructive. Most of the cases were for so advanced that the pet parents found out about IsoPet<sup>®</sup> on the Internet as a last hope. Several others were internal cancers that could not be reached, for example deep in the throat. Several cases were treatable, but the pets weighed more than 20 pounds and the pet parents were not willing to fly them in the “Safe Cargo” holds. Those patients would have been treated by regional clinics once we implement that strategy. Several cases were mast cell cancers. The Company is confident that those tumors could have been treated, but once killed they release mast cells in a process called granulation. This could cause a shock to the animal’s system. The Company will focus one of our clinical studies on the optimum approach for those therapies.

Vista Veterinary Hospital accepted advanced cancer cases and has gained experience to extend the animal’s lives. The first cat was terminally ill and had previously had external beam, surgery and chemotherapy. The facial tumor was treated with 400 Gy and the biopsy confirmed that the cancer was killed. In about seven months the cancer returned in the throat and could not be treated so the cat had to be put down. Dr. Bauder, the veterinarian pet parent, was still elated about the life extension and is asking us to use him as a reference. The other cases were also very advanced with multiple tumors and they recurred since they had already spread before therapy. One animal, Yukon had a large tumor on his leg that was recommended for amputation. The tumor size decreased 50% after the first treatment, but then stopped decreasing. For the first time a second therapy was administered and the tumor has continued to decrease in size. Yukon’s life was extended for more than a year until she finally succumbed to metastatic cancer in another location.

Since IsoPet<sup>®</sup> has shown to be effective in killing cancer at the site of injection the current focus is in optimizing the techniques to help the pet resorb the necrotic tissue rapidly. In addition, IsoPet<sup>®</sup> was used to treat a mast cell tumor. When these cancers are destroyed, they release their mast cell. The animal was treated with a steroid to counter this effect and to date is doing well.

The Company's efforts are now to obtain more early-stage cancer patients. The biggest obstacle is to convince the veterinarians of the pet parents to agree with IsoPet<sup>®</sup> therapy rather than using a more traditional method such as surgery. This is a slow process due to the conservative nature of the veterinarian professions. This is the prime motivation to continue with additional clinical trials and to publish the results.

The Company worked closely with FX Masse to develop nine certification training modules for use in potential regional clinics. These modules are necessary to satisfy the radioactive material handling licenses. This approach is very cost effective.

Johns Hopkins University VCTN, Veterinary Clinical Trials Network, is now an Isopet<sup>®</sup> regional clinic. Additionally, Johns Hopkins will also perform new Isopet<sup>®</sup> animal studies on various specific cancers. They have the required radioactive material license and have completed their training certification for Isopet<sup>®</sup>. This important relationship will also help meet our objective of obtaining high quality data on a range of cancers that can be published in leading journals. These publications are the optimal way to increase awareness of Isopet<sup>®</sup> and to gain broader acceptance from the veterinarian/oncology community.

Our objective is to open several regional clinics by the end of 2023 and to participate in a minimum of four conferences to spread the word about IsoPet in the veterinarian community for treating tumors in small animals and horses. We created a Marketing Steering Board to provide advice on obtaining new pet patients.

## **Regulatory History**

### *Human Therapy*

RadioGel<sup>™</sup> has a long regulatory history with the Food and Drug Administration ("FDA"). Initially, the Company submitted a pre-submission (Q130140) to obtain FDA feedback about the proposed product. The FDA requested that the Company file a request for designation with the Office of Combination Products (RFD130051), which led to the determination that RadioGel<sup>™</sup> is a device for human therapy for non-resectable cancers, which must be reviewed and ultimately regulated by the Center for Devices and Radiological Health ("CDRH"). The Company then submitted a 510(k) notice for RadioGel<sup>™</sup> (K133368), which was found Not Substantially Equivalent due to the lack of a suitable predicate, and RadioGel<sup>™</sup> was assigned to the Class III product code NAW (microspheres). Class III products or devices are generally the highest risk devices and are therefore subject to the highest level of regulatory review, control and oversight. Class III products or devices must typically be approved by FDA before they are marketed. Class II devices represent lower risk products or devices than Class III and require fewer regulatory controls to provide reasonable assurance of the product's or device's safety and effectiveness. In contrast, Class I products and devices are deemed to be lower risk than Class I or II, and are therefore subject to the least regulatory controls.

A pre-submission meeting (Q140496) was held with the FDA on June 17, 2014, during which the FDA maintained that RadioGel<sup>™</sup> should be considered a Class III device and therefore subject to pre-market approval. On December 29, 2014, the Company submitted a *de novo* petition for RadioGel<sup>™</sup> (DEN140043). The *de novo* petition was denied by the FDA on June 1, 2015, with the FDA providing numerous comments and questions. On September 29, 2015, the Company submitted a follow-up pre-submission informational meeting request with the FDA (Q151569). This meeting took place on November 9, 2015, at which time the FDA indicated acceptance of the Company's applied dosimetry methods and clarified the FDA's outstanding questions regarding RadioGel<sup>™</sup>. Following the November 2015 pre-submission meeting, the Company prepared a new pre-submission package to obtain FDA feedback on the proposed testing methods, intended to address the concerns raised by the FDA staff and to address the suitability of RadioGel<sup>™</sup> for *de novo* reclassification. This pre-submission package was presented to the FDA in a meeting on August 29, 2017. During the August 2017 meeting, the FDA clarified their position on the remaining pre-clinical testing needed for RadioGel<sup>™</sup>. Specifically, the FDA addressed proposed dosimetry calculating techniques, dosimetry distribution between injections, hydrogel viscoelastic properties, and the details of the Company's proposed animal testing.

The Company believes that its submissions to the FDA to date have addressed all the FDA staff's feedback over the past four years. Of particular importance, the Company has provided corresponding supporting data for proposed future testing of RadioGel™ to address any remaining questions raised by the FDA. We believe, although no assurances can be given, that the clinical testing modifications presented to the FDA in August 2017 will result in a *de novo* reclassification for RadioGel™ by the FDA. In addition, in previous FDA submissions, the Company proposed applying RadioGel™ for a very broad range of cancer therapies, referred to as Indication for Use. The FDA requested that the Company reduce its Indications for Use. To comply with that request, the Company expanded its Medical Advisory Board (“MAB”) and engaged doctors from respected hospitals who have evaluated the candidate cancer therapies based on three criteria: (1) potential for FDA approval and successful therapy; (2) notable advantage over current therapies; and (3) probability of wide-spread acceptance by the medical community.

In November 2020 the Company submitted a request for a Breakthrough Device Designation. Ultimately, this was denied, but the FDA acknowledged, “The FDA does believe that RadioGel™ meets criterion #2a: Device represents breakthrough technology. Your device *does meet this criterion* because it is a novel application of a brachytherapy device outside of the liver.” More importantly the process resulted in a rapid review of our existing data and approach. It led to a redirection of our efforts on writing the IDE and saved the Company much time in the review of that future application.

Based on advice from the FDA the Company has scheduled a Pre-Submission meeting on November 30, 2021 to discuss a draft of an Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies. Using this process results in more rapid feedback to prepare the final IDE.

The FDA was very supportive and had suggested this Q-Submission path for rapid turnaround and dialog. The Mayo Clinic physicians did an excellent job presenting the need for Radiogel™ to treat recurrent thyroid cancer and to answer a range of questions from the new FDA review team. The FDA provided many helpful suggestions on a range of subjects from labeling to dosimetry to the Mayo protocol for clinical testing, and the need for some additional specific testing. They suggested having another Q-Sub Review and conference call dedicated to the details of the dosimetry calculations.

In May of 2022 the Company held another Pre-Sub meeting with the FDA. They concurred with our dosimetry techniques and requested one more animal test to confirm that the Y-90 stays at the injection site. We will be proposed a Pre-Sub meeting to discuss this new animal test of VX-2 tumors in rabbits at Johns Hopkins University. We have a meeting scheduled with the FDA in October to obtain their feedback on our new animal test plan. In the meantime, the Company is working to complete all the other required pre-clinical testing, such as biocompatibility since they are required for the submittal of the IDE.

We held another Pre-Sub meeting with the FDA on October 17, 2022 to obtain detailed feedback on the proposed VX-2/Rabbit Animal Test Plan and to submit the Risk Management Report. The RMR analyzed all hypothetical scenarios and concluded that RadioGel is inherently safe.

In parallel the Company is working with the Mayo Clinic's principal investigators to improve the clinical trial protocol for their Institutional Review Board.

The MAB selected eighteen applications for RadioGel™, each of which meet the criteria described above. This large number confirms the wide applicability of the device and defines the path for future business growth. The Company's application establishes a single Indication for Use - treatment of cancerous tissue or solid tumors pathologically associated with locoregional papillary thyroid carcinoma and recurrent papillary thyroid carcinoma.

We anticipate that this initial application will facilitate each subsequent application for additional s Indications for Use. After the second indication for use we intend to applied for a broad indication for use, which would target to obtain approval to treat all solid tumors.

## Financing and Strategy

The Company's stock offering under Regulation A+ was qualified by the Securities and Exchange Commission ("SEC") on June 3, 2020. A second Regulation A+ was qualified by the SEC on September 15, 2021 to raise capital for 50,000,000 shares at a price of \$0.10 for a maximum of \$5,000,000. The Company amended this and was able to raise \$1,200,000 in July 2022 at \$0.08 per share (15,000,000 shares) and sold 20,000,000 warrants for \$20,000. An amended Regulation A+ was filed in October 2022 to raise the remaining \$3,800,000 of the \$5,000,000. In April 2023, \$640,000 was raised in the issuance of 8,000,000 common shares, 2,665,000 Series A warrants and 8,000,000 Series B warrants along with \$10,665 in the sale of warrants.

The Company's Regulation A+'s raised approximately \$5,200,000 from the sale of shares and is using the proceeds generated as follows:

For the animal therapy market:

- Fund the effort to communicate the benefits of IsoPet® to the veterinary community and the pet parents.
- Conduct additional clinical studies to generate more data for the veterinary community
- Subsidize some IsoPet® therapies, if necessary, to ensure that all viable candidates are treated.
- Assist a new regional clinic with their license and certification training.

For the human market:

- Enhance the pedigree of the Quality Management System.
- Complete the previously defined pre-clinical testing and additional testing on an animal model closely aligned with our revised indication for use. Report the results to the FDA in a pre-submission meeting.
- Use the feedback from that meeting to write the IDE (Investigational Device Exemption), which is required to initiate clinical trials.

Research and development of the Company's brachytherapy product line has been funded with proceeds from the sale of equity and debt securities. The Company may require additional funding of approximately \$2 million annually to maintain current operating activities. Over the next 12 to 24 months, the Company believes it will cost approximately \$9 million to: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet® across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States. The proceeds to be raised from the recent qualified Regulation A+ will be used to continue to fund this development.

The continued deployment of the brachytherapy products and a worldwide regulatory approval effort will require additional resources and personnel. The principal variables in the timing and amount of spending for the brachytherapy products in the next 12 to 24 months will be the FDA's classification of the Company's brachytherapy products as Class II or Class III devices (or otherwise) and any requirements for additional studies which may possibly include clinical studies. Thereafter, the principal variables in the amount of the Company's spending and its financing requirements would be the timing of any approvals and the nature of the Company's arrangements with third parties for manufacturing, sales, distribution and licensing of those products and the products' success in the U.S. and elsewhere. The Company intends to fund its activities through strategic transactions such as licensing and partnership agreements or from proceeds to be raised from the recent qualified Regulation A+.

Following receipt of required regulatory approvals and financing, in the U.S., the Company intends to outsource material aspects of manufacturing, distribution, sales and marketing. Outside of the U.S., the Company intends to pursue licensing arrangements and/or partnerships to facilitate its global commercialization strategy.

In the longer-term, subject to the Company receiving adequate funding, regulatory approval for RadioGel™ and other brachytherapy products, and thereafter being able to successfully commercialize its brachytherapy products, the Company intends to consider resuming research efforts with respect to other products and technologies intended to help improve the diagnosis and treatment of cancer and other illnesses.

Based on the Company's financial history since inception, the Company's independent registered public accounting firm has expressed substantial doubt as to the Company's ability to continue as a going concern. The Company has limited revenue, nominal cash, and has accumulated deficits since inception. If the Company cannot obtain sufficient additional capital, the Company will be required to delay the implementation of its business strategy and may not be able to continue operations.

As of June 30, 2023, the Company has \$1,748,767 cash on hand. There are currently commitments to vendors for products and services purchased. To continue the development of the Company's products, the current level of cash may not be enough to cover the fixed and variable obligations of the Company.

There is no guarantee that the Company will be able to raise additional funds or to do so at an advantageous price.

## **Product Features**

The Company's RadioGel™ device has the following product features:

- Beta particles only travel a short distance so the device can deliver high radiation to the tumor with minimal dose to the nearby normal tissues. In medical terms Y-90 beta emitter has a high efficacy rate;
- Benefitting from the short penetration distance, the patient can go home immediately with no fear of exposure to family members, and there is a greatly reduced radiation risk to the doctor. A simple plastic tube around the syringe, gloves and safety glasses are all that is required. Other gamma emitting products require much more protection;
- A 2.7-day half-life means that only 5% of the radiation remains after ten days. This is in contrast to the industry-standard gamma irradiation product, which has a half-life of 17 days;
- The short half-life also means that any medical waste can be stored for thirty days then disposed as normal hospital waste;
- RadioGel™ can be administered with small diameter needles (27-gauge) so there is minimal damage to the normal tissue. This is in contrast to the injection of metal seeds, which does considerable damage; and
- After about 120 days the gel resorbs by a normal biological cycle, called the Krebs Cycle. The only remaining evidence of the treatment are phosphate particles so small in diameter that it requires a high-resolution microscope to find them. This is in contrast to permanent presence of metal seeds.

## **Steps from Production to Therapy**

### *Device Production*

During the next two years, the Company intends to outsource material aspects of manufacturing and distribution. As future product volume increases, the Company will reassess its make-buy decision on manufacturing and will analyze the cost/benefit of a centrally located facility.

### *Production of the Hydrogel*

RadioGel™ is manufactured with a proprietary process under ventilated sterile hood by following strict Good Laboratory Practices ("GLP") procedures. It is made in large batches that are frozen for up to three months. When the product is ready to ship, a small quantity of the gel is dissolved in a sterile saline solution. It is then passed through an ultra-fine filter to ensure sterility.

### *Production of the Yttrium-90 Phosphate Particles*

The Y-90 particles are produced with simple ingredients via a proprietary process, again following strict GLP procedures. They are then mixed into a phosphate-buffered saline solution. They can be produced in large batches for several shipments. The number of particles per shipment is determined by the dose prescribed by the doctor.

### *Pre-Mixing – RTU, Ready to Use*

Vivos Inc now pre-mixes the particle solution and the hydrogel and places the RTU IsoPet in standard size vials. This innovation is cost effective and reduces the probability of any accidental spills or biological contamination at the therapy sites. It also simplified the certification training for new regional clinics.

### *Shipment*

The vials are shipped via FedEx or UPS by following the proper protocols.

### *At the User*

The quantities and activities are in the information on the product label.

The specific injection technique depends on the Indication for Use. For small tumors, one centimeter in diameter or less, the cancer is treated with a single injection. For larger tumors, the cancer is treated with a series of small injections from the same syringe or multiple syringes.

### **Principal Markets**

The Company is currently pursuing two synergistic business sectors, medical and veterinary, each of which are summarized below.

#### *Medical Sector*

RadioGel™ is currently fully developed, requiring only FDA approval before commercialization.

Building on the FDA's ruling of RadioGel™ as a device, the Company incorporated the FDA suggestions and has invested in the pre-clinical testing required for IDE submittal. This included two years of effort on biocompatibility testing. The last remaining animal test has been designed and has begun the initial scoping phase.

RadioGel™ is currently fully developed, requiring only FDA approval before commercialization. The Company has been seeking FDA approval of RadioGel™ for almost five years. Recent progress has been delayed due to a lack of adequate funding. The principal issue preventing approval is that the Company attempted to obtain regulatory approval for a broad range of Indications for Use, including all non-resectable cancers, without sufficient supporting data.

#### *Veterinary Sector*

There are approximately 150 million pet dogs and cats in the United States. Nearly one-half of dogs and one-third of cats are diagnosed with cancer at some point in their lifetime. The Veterinary Oncology & Hematology Center in Norwalk, Connecticut, reports that cancer is the number one natural cause of death in older cats and dogs, accounting for nearly 50 percent of pet deaths each year. The American Veterinary Medical Association reports that half of the dogs ten years or older will die because of cancer. The National Cancer Institute reports that about six million dogs are diagnosed with cancer each year, translating to more than 16,000 a day.

The Company's IsoPet® operating division focuses on the veterinary oncology market. Dr. Alice Villalobos, a founding member of the Veterinary Cancer Society and the Chair of our Veterinary Medicine Advisory Board, has been providing guidance to management regarding this market. The Veterinary Medicine Advisory Board gives us recommendations regarding the overall strategy for our animal business sector. Specially, they recommended the university veterinary hospitals for demonstration therapies, the specific cancers to be treated, and have provided business contact information to the private clinics.

Development of the product and application techniques and animal testing is allowed under FDA regulation. Commercial sales of RadioGel™ for animals requires confirmation by the FDA Center for Veterinary Medicine (“CVM”). In January 2018, the Center for Veterinary Medicine Product Classification Group, the entity within the CVM that is responsible for determining the classification of a product, ruled that RadioGel™ should be classified as a device for animal therapy of feline sarcomas and canine soft tissue sarcomas.

Additionally, after a legal review, the Company believes that the device classification obtained from the FDA Center for Veterinary Medicine is not limited to canine and feline sarcomas, but rather may be extended to a much broader population of veterinary cancers, including all or most all solid tumors in animals. We expect the result of such classification and label approval will be that no additional regulatory approvals are necessary for the use of RadioGel™ for the treatment of solid tumors in animals. The FDA does not have premarket authority over devices with a veterinary classification, and the manufacturers are responsible for assuring that the product is safe, effective, properly labeled, and otherwise in compliance with all applicable laws and regulations.

The Company currently intends to utilize university veterinary hospitals for therapy development, given that veterinary hospitals offer superior and plentiful veterinarians and students, a large number of animal patients, radioactive material handling licenses, and are respected by private veterinary centers and hospitals.

### **Competitors**

The Company competes in a market characterized by technological innovation, extensive research efforts, and significant competition.

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological changes. A number of companies are pursuing the development of pharmaceuticals and products that target the same diseases and conditions that our products target. We cannot predict with accuracy the timing or impact of the introduction of potentially competitive products or their possible effect on our sales. Certain potentially competitive products to our products may be in various stages of development. Also, there may be many ongoing studies with currently marketed products and other developmental products, which may yield new data that could adversely impact the use of our products in their current and potential future Indications for Use. The introduction of competitive products could significantly reduce our sales, which, in turn would adversely impact our financial and operating results.

There are a wide variety of cancer treatments approved and marketed in the U.S. and globally. General categories of treatment include surgery, chemotherapy, radiation therapy and immunotherapy. These products have a diverse set of success rates and side effects. The Company’s products, including RadioGel™, fall into the brachytherapy treatment category. There are a number of brachytherapy devices currently marketed in the U.S. and globally. The traditional iodine-125 (I-125) and palladium-103 (Pd-103) technologies for brachytherapy are well entrenched with powerful market players controlling the market. The industry-standard I-125-based therapy was developed by Oncura, which is a unit of General Electric Company. Additionally, C.R. Bard, a major industry player competes in the I-125 brachytherapy marketplace. These market competitors are also involved in the distribution of Pd-103 based products. Cs-131 brachytherapy products are sold by IsoRay. Several Y-90 therapies have been FDA approved including SIR-Spheres by Sirtex, TheraSphere by Biocompatibles UK and Zevalin by Spectrum Pharmaceuticals.

### **Raw Materials**

The Company currently subcontracts the manufacturing of RadioGel™ at IsoTherapeutics. Prior to 2021, Eckert and Ziegler was the only supplier of Y-90 in the United States, and was the sole supplier of the Y-90 used by IsoTherapeutics to manufacture the Company's RadioGel™. The Company obtains supplies, hardware, handling equipment and packaging from several different U.S. suppliers.

During 2021, the Company engaged Akina, Inc. as an alternate supplier of its hydrogel polymer component. We have now expanded to include SciPoly as another alternate polymer supplier.

In the future we will be looking to qualify an alternative particle supplier.

### **Customers**

The Company anticipates that potential customers for our potential brachytherapy products likely would include those institutions and individuals that currently purchase brachytherapy products or other oncology treatment products.

### **Government Regulation**

The Company's present and future intended activities in the development, manufacturing and sale of cancer therapy products, including RadioGel™, are subject to extensive laws, regulations, regulatory approvals and guidelines. Within the United States, the Company's therapeutic radiological devices must comply with the U.S. Federal Food, Drug and Cosmetic Act, which is enforced by FDA. The Company is also required to adhere to applicable FDA Quality System Regulations, also known as the Good Manufacturing Practices, which include extensive record keeping and periodic inspections of manufacturing facilities.

In the United States, the FDA regulates, among other things, new product clearances and approvals to establish the safety and efficacy of these products. We are also subject to other federal and state laws and regulations, including the Occupational Safety and Health Act and the Environmental Protection Act.

The Federal Food, Drug, and Cosmetic Act and other federal statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, distribution, use, reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications, disqualification from sponsoring or conducting clinical investigations, preventing us from entering into government supply contracts, withdrawal of previously approved applications, and criminal prosecution.

In the United States, medical devices are classified into three different categories over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Most Class I devices are exempt from premarket notification 510(k); most Class II devices require premarket notification 510(k); and most Class III devices require premarket approval. RadioGel™ is currently classified as a Class III device.

Approval of new Class III medical devices is a lengthy procedure and can take a number of years and require the expenditure of significant resources. There is a shorter FDA review and clearance process for Class II medical devices, the premarket notification or 510(k) process, whereby a company can market certain Class II medical devices that can be shown to be substantially equivalent to other legally marketed devices.

The Company intends to apply for a *de novo* with an anticipated expenditure of \$10.0 million over the next four years. This expenditure estimate includes anticipated costs associated with in vitro and in vivo pre-clinical testing, our application for an Investigational Device Exemption, Phase I and Phase II clinical trials and our application for a *de novo*.

As a registered medical device manufacturer with the FDA, we are subject to inspection to ensure compliance with FDA's current Good Manufacturing Practices, or cGMP. These regulations require that we and any of our contract manufacturers design, manufacture and service products, and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control, and service activities. Modifications or enhancements that could significantly affect the safety or effectiveness of a device or that constitute a major change to the intended use of the device require a new 510(k) premarket notification for any significant product modification.

The Medical Device Reporting regulation requires that we provide information to the FDA on deaths or serious injuries alleged to be associated with the use of our devices, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. Labeling and promotional activities are regulated by the FDA and, in some circumstances, by the Federal Trade Commission.

As a medical device manufacturer, we are also subject to laws and regulations administered by governmental entities at the federal, state and local levels. For example, our facility is licensed as a medical device manufacturing facility in the State of Washington and is subject to periodic state regulatory inspections. Our customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive byproduct material, we are subject to extensive regulation by not only federal governmental authorities, such as the FDA and FAA, but also by state and local governmental authorities, such as the Washington State Department of Health, to ensure such devices are safe and effective. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission (“NRC”), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. RadioGel™ constitutes both medical devices and radioactive sealed sources and are subject to these regulations.

Moreover, our use, management, and disposal of certain radioactive substances and wastes are subject to regulation by several federal and state agencies depending on the nature of the substance or waste material. We believe that we are in compliance with all federal and state regulations for this purpose.

### ***Environmental Regulation***

Our business does not require us to comply with any extraordinary environmental regulations. Our RadioGel™ product is manufactured in an independently owned and operated facility. Any environmental effects or contamination event that could result would be from the shipping company during shipment and misuse by the treatment facility upon arrival.

### ***Human Capital***

As of June 30, 2023, the Company had one full-time personnel. The Company utilizes several independent contractors to assist with its operations. The Company does not have a collective bargaining agreement with any of its personnel and believes its relations with its personnel are good.

### **Results of Operations**

#### **Comparison of the Six Months Ended June 30, 2023 and 2022**

The following table sets forth information from our statements of operations for the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Revenues	\$ 12,500	\$ 23,500
Cost of goods sold	(16,536)	(5,018)
Gross (loss) profit	(4,036)	18,482
Operating expenses	(1,158,687)	(1,553,513)
Operating loss	(1,162,723)	(1,535,031)
Non-operating income (expense)	11,879	47,588
Net loss	\$ (1,150,844)	\$ (1,487,443)

### **Revenues and Cost of Goods Sold**

Revenue was \$12,500 and \$23,500 for the six months ended June 30, 2023 and 2022, respectively. All revenue recognized in the six months ended June 30, 2023 and 2022 relate to consulting income with respect to the IsoPet® therapies.

Management does not anticipate that the Company will generate sufficient revenue to sustain operations until such time as the Company secures multiple revenue-generating arrangements with respect to RadioGel™ and/or any of our other brachytherapy technologies.

### **Operating Expenses**

Operating expenses for the six months ended June 30, 2023 and 2022, respectively consists of the following:

	Six months ended June 30, 2023	Six months ended June 30, 2022
Professional fees, including stock-based compensation	\$ 692,963	\$ 1,098,507
Payroll expenses	144,521	140,656
Research and development	219,728	241,301
General and administrative expenses	101,475	73,049
Total operating expenses	<u>\$ 1,158,687</u>	<u>\$ 1,553,513</u>

Operating expenses for the six months ended June 30, 2023 and 2022 was \$1,158,687 and \$1,553,513, respectively. The decrease in operating expenses from 2022 to 2023 can be attributed to the decrease in professional fees (\$1,098,507 for the six months ended June 30, 2022 versus \$692,963 for the six months ended June 30, 2023) related to the patent and trademark protection the Company undertook in mid 2022 offset by the reduction in stock based compensation related to the RSUs in 2022 versus 2023; the increase in general and administrative expense (\$73,049 for the six months ended June 30, 2022 versus \$101,475 for the six months ended June 30, 2023); the decrease in research and development (\$241,301 for the six months ended June 30, 2022 versus \$219,728 for the six months ended June 30, 2023) as the Company ramped up the development of their products in 2022 versus 2023 to include studies that are required to continue to have their products accepted by the FDA, and an increase in payroll expenses (\$140,656 for the six months ended June 30, 2022 versus \$144,521 for the six months ended June 30, 2023) related to the CEOs employment contract and bonus.

### **Non-Operating Income (Expense)**

Non-operating income (expense) for the six months ended June 30, 2023 and 2022 consists of the following:

	Six months ended June 30, 2023	Six months ended June 30, 2022
Gain on debt extinguishment	\$ -	\$ 47,588
Interest income	11,879	-
Non-operating income (expense)	<u>\$ 11,879</u>	<u>\$ 47,588</u>

Non-operating income (expense) for the six months ended June 30, 2022 related to the settlement of debt on old payables as they satisfied agreements with vendors to pay a portion of the payable with the remaining amount forgiven, versus 2023 which represents interest earned on the Company's cash accounts.

### Net Loss

Our net loss for the six months ended June 30, 2023 and 2022 was \$(1,150,844) and \$(1,487,443), respectively.

### Comparison of the Three Months Ended June 30, 2023 and 2022

The following table sets forth information from our statements of operations for the three months ended June 30, 2023 and 2022:

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022
Revenues	\$ 6,500	\$ 10,500
Cost of goods sold	(9,000)	(2,018)
Gross (loss) profit	(2,500)	8,482
Operating expenses	(911,905)	(796,020)
Operating loss	(914,405)	(787,538)
Non-operating income (expense)	11,879	-
Net loss	\$ (902,526)	\$ (787,538)

### Revenues and Cost of Goods Sold

Revenue was \$6,500 and \$10,500 for the three months ended June 30, 2023 and 2022, respectively. All revenue recognized in the three months ended June 30, 2023 and 2022 relate to consulting income with respect to the IsoPet<sup>®</sup> therapies.

Management does not anticipate that the Company will generate sufficient revenue to sustain operations until such time as the Company secures multiple revenue-generating arrangements with respect to RadioGel<sup>™</sup> and/or any of our other brachytherapy technologies.

### Operating Expenses

Operating expenses for the three months ended June 30, 2023 and 2022, respectively consists of the following:

	Three months ended June 30, 2023	Three months ended June 30, 2022
Professional fees, including stock-based compensation	\$ 608,747	\$ 521,470
Payroll expenses	72,013	69,869
Research and development	173,353	169,732
General and administrative expenses	57,792	34,949
Total operating expenses	\$ 911,905	\$ 796,020

Operating expenses for the three months ended June 30, 2023 and 2022 was \$911,905 and \$796,020, respectively. The increase in operating expenses from 2022 to 2023 can be attributed to the increase in professional fees (\$521,470 for the three months ended June 30, 2022 versus \$608,747 for the three months ended June 30, 2023) related to the stock based compensation related to the RSUs in 2023 versus 2022; the increase in general and administrative expense (\$34,949 for the three months ended June 30, 2022 versus \$57,792 for the three months ended June 30, 2023); the increase in research and development (\$169,732 for the three months ended June 30, 2022 versus \$173,353 for the three months ended June 30, 2023) as the Company continued to ramp up the development of their products in 2023 to include studies that are required to continue to have their products accepted by the FDA, and an increase in payroll expenses (\$69,869 for the three months ended June 30, 2022 versus \$72,013 for the three months ended June 30, 2023) related to the CEOs employment contract and bonus.

### Non-Operating Income (Expense)

Non-operating income (expense) for the three months ended June 30, 2023 and 2022 consists of the following:

	Three months ended June 30, 2023	Three months ended June 30, 2022
Interest income	\$ 11,879	\$ -
Non-operating income (expense)	\$ 11,879	\$ -

Non-operating income (expense) for the three months ended June 30, 2023 related to interest earned on the Company's cash accounts.

### Net Loss

Our net loss for the three months ended June 30, 2023 and 2022 was \$(902,526) and \$(787,538), respectively.

## **Liquidity and Capital Resources**

At June 30, 2023, the Company had working capital of \$1,676,840, as compared to working capital of \$1,661,044 at December 31, 2022. During the six months ended June 30, 2023 and 2022, the Company experienced negative cash flow from operations of \$607,963 and \$555,417 and had no cash from investing activities. In 2023, the Company raised \$650,665 in the sale of common stock and warrants under the Reg A+ as part of their financing activities. As of June 30, 2023, the Company did not have any commitments for capital expenditures.

Cash used in operating activities increased from \$555,417 for the six months ended June 30, 2022 to \$607,963 for the six months ended June 30, 2023. Cash used in operating activities was primarily a result of the Company's non-cash items, such as loss from operations, stock based compensation, loss conversion of debt as well as forgiveness of debt as well as the changes in prepaid expenses and accounts payable in 2022 compared to only having net changes from current assets and liabilities and stock based compensation in 2023.

The Company has generated material operating losses since inception. The Company had a net loss of \$1,150,844 for the six months ended June 30, 2023, and a net loss of \$1,487,443 for the six months ended June 30, 2022. The Company expects to continue to experience net operating losses for the foreseeable future. Historically, the Company has relied upon investor funds to maintain its operations and develop the Company's business. The Company anticipates raising additional capital within the next twelve months for working capital as well as business expansion, although the Company can provide no assurance that additional capital will be available on terms acceptable to the Company, if at all. If the Company is unable to obtain additional financing to meet its working capital requirements, it may have to curtail its business or cease all operations.

The Company requires funding of at least \$5 million per year to maintain current operating activities. Over the next 24 months, the Company believes it will cost approximately \$9 million to fund: (1) fund the FDA approval process to conduct human clinical trials, (2) conduct Phase I, pilot, clinical trials, (3) activate several regional clinics to administer IsoPet<sup>®</sup> across the county, (4) create an independent production center within the current production site to create a template for future international manufacturing, and (5) initiate regulatory approval processes outside of the United States. In April 2023, \$640,000 was raised in the issuance of 8,000,000 common shares, 2,665,000 Series A warrants and 8,000,000 Series B warrants along with \$10,665 in the sale of warrants.

The principal variables in the timing and amount of spending for the brachytherapy products in the next 12 to 24 months will be the FDA's classification of the Company's brachytherapy products as Class II or Class III devices (or otherwise) and any requirements for additional studies, which may possibly include clinical studies. Thereafter, the principal variables in the amount of the Company's spending and its financing requirements would be the timing of any approvals and the nature of the Company's arrangements with third parties for manufacturing, sales, distribution and licensing of those products and the products' success in the U.S. and elsewhere. The Company intends to fund its activities through strategic transactions such as licensing and partnership agreements or additional capital raises.

Although the Company is seeking to raise additional capital and has engaged in numerous discussions with investment bankers and investors, to date, the Company has not received firm commitments for the required funding. Based upon its discussions, the Company anticipates that if the Company is able to obtain the funding required to retire outstanding debt, pay past due payables and maintain its current operating activities, that the terms associated with such funding will result in material dilution to existing shareholders.

Recent geopolitical events, including the inherent instability and volatility in global capital markets, as well as the lack of liquidity in the capital markets, could impact the Company's ability to obtain financing and its ability to execute its business plan.

Our Chief Executive Officer currently works from his home office in virtual communication with key personnel. Cadwell Laboratories, which is controlled by Carl Cadwell, a director of the Company, provides office space to management on an as-needed basis until such time as the Company leases permanent office space.

## **Accounting Policies and Estimates**

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed financial statements and accompanying notes. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions. During the period ended June 30, 2023, we believe there have been no significant changes to the items disclosed as significant accounting policies in management's notes to the financial statements in our annual report on Form 10-K for the year ended December 31, 2022, filed on March 1, 2023.

## **Off-Balance Sheet Arrangements**

The Company does not have any off-balance sheet arrangements that are reasonably likely to have a current or future effect on the Company's financial condition, revenues, results of operations, liquidity or capital expenditures.

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

This item is not applicable to us because we are a smaller reporting company as defined by Rule 12b-2 under the Securities Exchange Act of 1934.

### **Item 4. Controls and Procedures.**

#### **Disclosure Controls and Procedures**

Based on an evaluation as of the date of the end of the period covered by this report, the Company's Chief Executive Officer and Interim Chief Financial Officer conducted an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures, as required by Exchange Act Rule 13a-15. Based on that evaluation, the Company's Chief Executive Officer and Interim Chief Financial Officer concluded that, because of the disclosed material weaknesses in the Company's internal control over financial reporting, the Company's disclosure controls and procedures were ineffective as of the end of the period covered by this report to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in the Company's reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the Company's reports filed under the Exchange Act is accumulated and communicated to management, including the Company's Chief Executive Officer and the Company's Interim Chief Financial Officer, to allow timely decisions regarding required disclosure.

#### **Changes in Internal Control Over Financial Reporting**

There have been no changes in the Company's internal control over financial reporting that occurred during the period ended June 30, 2023 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

The term "internal control over financial reporting" is defined as a process designed by, or under the supervision of, the registrant's principal executive and principal financial officers, or persons performing similar functions, and effected by the registrant's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- (a) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the registrant;
- (b) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the registrant are being made only in accordance with authorizations of management and directors of the registrant; and
- (c) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the registrant's assets that could have a material effect on the financial statements.

## PART II

### Item 1. Legal Proceedings

The Company may, from time to time, be involved in various legal proceedings incidental to the conduct of our business. Historically, the outcome of all such legal proceedings has not, in the aggregate, had a material adverse effect on our business, financial condition, results of operations or liquidity.

### Item 2. Unregistered Sales of Equity Securities

In March 2022, the Company issued 299,577 shares of common stock in the cashless exercise of 825,000 warrants, and 76,250 shares of common stock for services rendered to the CEO.

On July 7, 2022, the Company sold 15,000,000 shares under the Regulation A+ at \$0.08 for \$1,200,000, and 20,000,000 warrants (15,000,000 at \$0.08 expiring June 2025 and 5,000,000 at \$0.01 expiring December 2022) for \$20,000.

In September 2022, the Company issued 984,840 shares of common stock valued at \$49,242 in settlement of accounts payable.

In December 2022, the Company issued 2,650,273 shares of common stock in the cashless exercise of 3,333,333 warrants.

In April 2023, the Company sold 8,000,000 shares under the Regulation A+ at \$0.08 for \$640,000, and 10,665,000 warrants (8,000,000 at \$0.10 expiring June 2026 and 2,665,000 at \$0.01 expiring December 2023) for \$10,665.

In connection with the above stock sales, we did not pay any underwriting discounts or commissions. None of the sales of securities described or referred to above was registered under the Securities Act of 1933, as amended (the "Securities Act"). For sales made pursuant to an exemption from registration contained in Section 4(a)(2) of the Securities Act, no general solicitation was used in connection with the sales.

### Item 6. Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
31.1*	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes – Oxley Act of 2002</a>
31.2*	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes – Oxley Act of 2002</a>
32.1*	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350</a>
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\* Filed herewith.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Vivos Inc.

Date: August 4, 2023

By: /s/ Michael Korenko

Name: Michael K. Korenko

Title: Chief Executive Officer  
(Principal Executive Officer)

Date: August 4, 2023

By: /s/ Michael Pollack

Name: Michael Pollack

Title: Interim Chief Financial Officer  
(Interim Principal Financial and Accounting Officer)

**EXHIBIT 31.1**

CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael K. Korenko, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vivos Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2023

/s/ Michael K. Korenko

Michael K. Korenko  
Chief Executive Officer  
(Principal Executive Officer)

---

**EXHIBIT 31.2**

CERTIFICATION OF INTERIM CHIEF FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Pollack, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vivos Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2023

/s/ Michael Pollack

Michael Pollack  
Interim Chief Financial Officer  
(Interim Principal Financial Officer)

---

**EXHIBIT 32.1**

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

In connection with the accompanying quarterly report of Vivos Inc. (the "*Company*") on Form 10-Q for the quarter ended June 30, 2023 (the "*Report*"), the undersigned, Michael Korenko, Chief Executive Officer of the Company, and Michael Pollack, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 4, 2023

/s/ Michael K. Korenko

Name: Michael K. Korenko

Title: Chief Executive Officer

/s/ Michael Pollack

Name: Michael Pollack

Title: Interim Chief Financial Officer

---