# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended September 30, 2022 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 П For the transition period from Commission File Number: 0-51891 INTERNATIONAL STEM CELL CORPORATION (Exact name of Registrant as specified in its charter) Delaware 20-4494098 (State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification No.) 5950 Priestly Drive 92008 Carlshad, CA (Address of Principal Executive Offices) (Zip Code) (760) 940-6383 (Registrant's telephone number) Securities registered pursuant to Section 12(b) of the Act: Trading Title of each class Symbol(s) Name of each exchange on which registered Indicated 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 X NO 🗆 Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES X NO  $\square$ Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. Accelerated filer Large accelerated filer П Χ Non-accelerated filer Smaller reporting company Χ Emerging growth company If an emerging growth company, indicate by check mark if the registrant 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  $\square$  NO X Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

As of November 9, 2022, the Registrant had 8,004,389 shares of Common Stock outstanding.

# $International\ Stem\ Cell\ Corporation\ and\ Subsidiaries$

# Form 10-Q

# **Table of Contents**

PART I—FINANO	CIAL INFORMATION	Page Numbers
Item 1.	Condensed Consolidated Financial Statements (Unaudited)	3
	Condensed Consolidated Balance Sheets as of September 30, 2022 (Unaudited) and December 31, 2021	3
	Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2022 and 2021 (Unaudited)	4
	Condensed Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit for the three and	•
	nine months ended September 30, 2022 and 2021 (Unaudited)	5
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2022 and 2021 (Unaudited)	6
	Notes to Condensed Consolidated Financial Statements (Unaudited)	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3.	Ouantitative and Oualitative Disclosures About Market Risk	28
Item 4.	Controls and Procedures	29
	R INFORMATION	
Item 1.	<u>Legal Proceedings</u>	30
Item 1A.	Risk Factors	30
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
Item 3.	<u>Defaults Upon Senior Securities</u>	30
Item 4.	Mine Safety Disclosures	30
Item 5.	Other Information	30
Item 6.	<u>Exhibits</u>	31
	Signatures Signatures	32
	2	

# PART I – FINANCIAL INFORMATION

# Item 1. Condensed Consolidated Financial Statements

# International Stem Cell Corporation and Subsidiaries Condensed Consolidated Balance Sheets (In thousands, except share and par value data) (Unaudited)

		ember 30, 2022	De	ecember 31, 2021
	(una	audited)		
Assets				
Current assets:				
Cash	\$	666	\$	171
Accounts receivable, net		427		844
Inventory, net		1,415		1,184
Prepaid expenses and other current assets		192		135
Total current assets		2,700		2,334
Non-current inventory, net		369		372
Property and equipment, net		279		384
Intangible assets, net		896		949
Operating lease right-of-use assets		764		868
Deposits and other assets		34		39
Total assets	\$	5,042	\$	4,946
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit				
Current liabilities:				
Accounts payable	\$	378	\$	508
Accrued liabilities		475		404
Operating lease liabilities, current		219		179
Advances		250		250
Related party note payable		3,291		2,943
Total current liabilities		4,613		4,284
Operating lease liabilities, net of current portion		781		950
Total liabilities		5,394		5,234
Commitments and contingencies (Note 8)			_	-, -
Series D redeemable convertible preferred stock, \$0.001 par value; 50 shares				
authorized; 43 shares issued and outstanding; liquidation preference of \$4,300				
at September 30, 2022 and December 31, 2021		4,300		4,300
Stockholders' deficit:				
Non-redeemable convertible preferred stock, \$0.001 par value; 10,004,310				
shares authorized; 5,254,310 shares issued and outstanding; liquidation				
preference of \$9,778 and \$9,766 at September 30, 2022 and December 31, 2021, respectively		5		5
Common stock, \$0.001 par value; 120,000,000 shares authorized; 8,004,389				
shares issued and outstanding at September 30, 2022 and December 31, 2021		8		8
Additional paid-in capital		105,703		105,413
Accumulated deficit		(110,368)		(110,014)
Total stockholders' deficit		(4,652)		(4,588)
Total liabilities, redeemable convertible preferred stock		<u></u>		
and stockholders' deficit	\$	5,042	\$	4,946

# International Stem Cell Corporation and Subsidiaries Condensed Consolidated Statements of Operations (In thousands, except per share data) (Unaudited)

	Th	ree Months End	led Septe	ember 30,	N	line Months End	ed Septe	ember 30,
		2022		2021		2022		2021
Product sales, net	\$	1,703	\$	1,842	\$	5,750	\$	5,333
Operating expenses:								
Cost of sales		690		814		2,133		2,200
Research and development		147		165		367		492
Selling and marketing		358		352		982		1,049
General and administrative		808		1,134		2,512		3,190
Total operating expenses		2,003		2,465		5,994		6,931
Loss from operations		(300)		(623)		(244)		(1,598)
Other income (expense):								
Cain on forgiveness of debt		-		476		-		1,137
Interest expense (includes related party amounts of \$33, \$30, \$98, and \$87,								
respectively)		(35)		(31)		(102)		(97)
Other income (expense), net		(8)		13		(8)		10
Total other income (expense), net		(43)		458		(110)		1,050
Net loss	\$	(343)	\$	(165)	\$	(354)	\$	(548)
Net loss per common share, basic and diluted	\$	(0.04)	\$	(0.02)	\$	(0.04)	\$	(0.07)
Weighted-average common shares used to compute								
net loss per share, basic and diluted		8,004		8,004		8,004		7,772

# International Stem Cell Corporation and Subsidiaries Condensed Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit (In thousands) (Unaudited)

Three and Nine Months Ended September 30, 2022

	Series D R	edeemable	Non-red	leemable										
	Conve	ertible	Conv	Convertible		Common			Ad	lditional			Total	
	Preferre	ed Stock	Preferred Stock				Stock		Paid-in		Accumulated		Stockholders'	
	Shares	Amount	Shares Amount			Shares Amount		ınt	Capital		Deficit		Deficit	
Balance at December 31, 2021	_	\$ 4,300	5,254	\$	5	8,004	\$	8	\$	105,413	\$	(110,014)	\$ (4,588)	
Stock-based compensation	_	_	_	_	_	_		—		91		_	91	
Net loss	_	_	_	-	_	_		_		_		(9)	(9)	
Balance at March 31, 2022		4,300	5,254		5	8,004		8		105,504		(110,023)	(4,506)	
Stock-based compensation						_				90			90	
Net loss	_			-	_	_		_		_		(2)	(2)	
Balance at June 30, 2022		4,300	5,254		5	8,004		8		105,594		(110,025)	(4,418)	
Stock-based compensation				_						109			109	
Net loss	_	_	_	-	_	_		_		_		(343)	(343)	
Balance at September 30, 2022		\$ 4,300	5,254	\$	5	8,004	\$	8	\$	105,703	\$	(110,368)	\$ (4,652)	
	·					<del></del>								

_				Three and Nine	Months End	ed September	r 30, 2021			
	Series D R	edeemable	Non-red	deemable						
	Conve	rtible	Conv	ertible	Con	nmon	Additional		Total	
_	Preferre	ed Stock	Preferr	ed Stock	St	ock	Paid-in	Accumulated	Stockholders'	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit	
Balance at December 31, 2020	_	\$ 4,300	5,255	\$ 5	7,539	\$ 8	\$ 104,769	\$ (109,115)	\$ (4,333)	
Stock-based compensation	_	_	-	_	_	_	234	_	234	
Net loss	_	_	-	_	_	_	_	(599)	(599)	
Balance at March 31, 2021	_	4,300	5,255	5	7,539	8	105,003	(109,714)	(4,698)	
Conversion of Series I-1 preferred stock	_	_	(1)	_	465	_	_	_	_	
Stock-based compensation	_	_	-	_	_	_	172	_	172	
Net income	<u> </u>							216	216	
Balance at June 30, 2021	_	4,300	5,254	5	8,004	8	105,175	(109,498)	(4,310)	
Stock-based compensation	_	_	-	_	_	_	118	_	118	
Net loss			-					(165)	(165)	
Balance at September 30, 2021		\$ 4,300	5,254	\$ 5	8,004	\$ 8	\$ 105,293	\$ (109,663)	\$ (4,357)	

# International Stem Cell Corporation and Subsidiaries Condensed Consolidated Statements of Cash Flows (In thousands) (Unaudited)

		Nine Months Ended Sep	tember 30,
		2022	2021
Cash flows from operating activities			
Net loss	\$	(354) \$	(548)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization		166	195
Non-cash operating lease expense		104	215
Impairment of intangible assets		_	250
Loss on disposal of property and equipment		_	4
Stock-based compensation		290	524
Gain on forgiveness of debt		_	(1,137)
Interest expense on related party note payable		98	87
Changes in operating assets and liabilities:			
Accounts receivable, net		417	(265)
Inventory, net		(228)	(216)
Prepaid expenses and other current assets		(57)	_
Deposits and other assets		5	17
Accounts payable		(130)	251
Accrued liabilities		71	(104)
Operating lease liabilities		(129)	(254)
Net cash provided by (used in) operating activities		253	(981)
Cash flows from investing activities			
Purchase of property and equipment		(1)	(13)
Payments for patent licenses		(7)	(14)
Net cash used in investing activities		(8)	(27)
Cash flows from financing activities			
Proceeds from Paycheck Protection Program loans		_	474
Proceeds from related party note payable		250	350
Net cash provided by financing activities		250	824
Net increase (decrease) in cash		495	(184)
Cash at beginning of period		171	689
Cash at end of period	\$	666 \$	505
Supplemental disclosure of non-cash investing and financing activities:			
Gain on forgiveness of debt	\$	- \$	1,137
Patent license costs included in accrued liabilities	\$	- \$	7
Tarent method costs managed in decided incoming	Ψ	Ψ	

# International Stem Cell Corporation and Subsidiaries Notes to Condensed Consolidated Financial Statements (Unaudited)

### 1. Description of Business, Basis of Presentation and Summary of Significant Accounting Policies

# Description of Business

International Stem Cell Corporation (the "Company") was organized in Delaware in June 2005 and is headquartered in San Diego, California. The Company is primarily a research and development company for the therapeutic market, which has focused on advancing potential clinical applications of human parthenogenetic stem cells ("hpSCs") for the treatment of various diseases of the central nervous system and liver. The Company has the following wholly owned subsidiaries:

- Lifeline Cell Technology, LLC ("LCT") for the biomedical market, develops, manufactures and commercializes primary human cell research products, including over 200 human cell culture products such as frozen human "primary" cells and the reagents (called "media") needed to grow, maintain and differentiate the cells;
- Lifeline Skin Care, Inc. ("LSC") for the anti-aging market, develops, manufactures and markets a category of anti-aging skin care products based on the Company's proprietary parthenogenetic stem cell technology and small molecule technology;
- Cyto Therapeutics Pty. Ltd. ("Cyto Therapeutics") performs research and development ("R&D") for the therapeutic market and is currently conducting clinical trials in Australia for the use of ISC-hpNSC® in the treatment of Parkinson's disease.

### COVID-19 Pandemic

The COVID-19 pandemic has caused business disruptions in the Company's operations globally. The Company's condensed consolidated financial statements reflect judgments and estimates that could change in the future as a result of the COVID-19 pandemic. Impacts to the Company's business have included temporary or reduced occupancy of portions of its manufacturing facilities, and disruptions or restrictions on employee's ability to travel to such manufacturing facilities, which have caused minor delays in manufacturing. As of the date of this report, the Company expects the COVID-19 pandemic may continue to impact its business, financial condition, liquidity, and future results of operations. The full extent to which the COVID-19 pandemic has and may continue to impact the Company remains uncertain and ultimately will be dictated by the length and severity of the pandemic as well as the economic recovery and federal, state, and local government actions taken in response. The Company will continue to monitor the impact of COVID-19 on the Company's operations, workforce, suppliers, customers, and industry.

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") applicable to interim financial statements. Certain information and notes normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations. The unaudited interim condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company's condensed consolidated financial statements. The operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2022. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2021 included in the Company's annual report on Form 10-K filed with the SEC on March 29, 2022.

# Liquidity and Going Concern

The Company had an accumulated deficit of approximately \$110.4 million as of September 30, 2022 and has incurred net losses and negative operating cash flows annually, since inception. The Company has generated no revenue from its therapeutic product candidates. Unless the Company obtains additional financing, the Company does not have sufficient cash on hand to sustain operations for at least twelve months from the issuance date of these condensed consolidated financial statements.

There can be no assurance that the Company will be successful in maintaining normal operating cash flow or obtaining additional funding. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional financing. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability

and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

The Company continues to evaluate various financing sources and options to raise working capital to help fund current research and development programs and operations. The Company plans to obtain significant additional funding from sources, including through debt and equity financing, license arrangements, grants and/or collaborative research arrangements to sustain its operations and develop products.

The timing and degree of any future capital requirements will depend on several factors, including:

- the accuracy of the assumptions underlying the estimates for capital needs;
- the extent that revenues from sales of LSC and LCT products cover the related costs and provide capital;
- scientific progress in research and development programs;
- the magnitude and scope of the Company's research and development programs and its ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the progress with preclinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the number and type of product candidates that the Company decides to pursue;
- · demand from the Company's largest original equipment manufacturer customers; and
- the development of major public health concerns, including COVID-19 or other pandemics arising globally, and the current and future impact that such concerns may have on the Company's operations and funding requirements.

Additional debt financing may be expensive and require the Company to pledge all or a substantial portion of its assets. If additional funds are obtained through arrangements with collaborative partners, these arrangements may require the Company to relinquish the rights to some of its technologies, product candidates, or products that the Company would otherwise seek to develop and commercialize on its own. Furthermore, if sufficient capital is not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its product initiatives. The Company's failure to raise capital or enter into related arrangements when needed would have a negative impact on its financial condition

# Principles of Consolidation and Foreign Currency Transactions

The condensed consolidated financial statements include the accounts of International Stem Cell Corporation and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The functional currency of the Company and its wholly owned subsidiaries is the U.S. dollar. Monetary assets and liabilities that are not denominated in the functional currency are remeasured each reporting period into U.S. dollars at foreign currency exchange rates in effect at the respective balance sheet date. Non-monetary assets and liabilities and equity are remeasured at the historical exchange rates. Revenue and expenses are remeasured at the average rate in effect on the date of the transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in general and administrative expense in the accompanying condensed consolidated statements of operations and were not material for the periods presented.

# Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Significant estimates include patent life (remaining legal life versus remaining useful life), inventory carrying values, and the fair value of stock option grants using the Black-Scholes option valuation model. By their nature, estimates are subject to an inherent degree of uncertainty and actual results could differ from these estimates.

### Segments

The Company's chief operating decision-maker reviews financial information presented on a consolidated basis, accompanied by disaggregated information for each reportable company's statement of operations. The Company operates the business on the basis of three reporting segments: ISCO – therapeutic market; LCT – biomedical market, and; LSC – anti-aging market.

## Inventory, net

Inventory is accounted for using the average cost and first-in, first-out ("FIFO") methods for LCT cell culture media and reagents, average cost and specific identification method for other LCT products. Inventory balances are stated at the lower of cost or net realizable value. Laboratory supplies used in the research and development process are expensed as consumed. LCT's inventory has a long product life cycle, does not have a shelf life when frozen, and future demand is uncertain. At each reporting period, the Company estimates its reserve allowance for excess and obsolete inventory using historical sales data and inventory turnover rates. The establishment of a reserve for excess and obsolete inventory establishes a new cost basis in inventory. If the Company is able to sell previously reserved inventory, the related reserves and inventory balances would be reduced in the period of sale. The value of the inventory that is not expected to be sold within twelve months of the current reporting period is classified as non-current inventory on the accompanying condensed consolidated balance sheets.

### Accounts Receivable, net

Trade accounts receivable are recorded at the invoice value, net of discounts, and are not interest bearing. Accounts receivable primarily consist of trade accounts receivable from the sales of LCT's products as well as LSC trade receivable amounts related to spa and distributor sales. The Company considers receivables past due based on the contractual payment terms. The Company reviews its exposure to accounts receivable and reserves specific amounts if collectability is no longer reasonably assured. The Company recorded an immaterial amount pertaining to the allowance for doubtful accounts as of September 30, 2022 and December 31, 2021.

# Intangible Assets

Intangible assets consist of acquired patent licenses and capitalized legal fees related to the acquisition, filing, maintenance, and defense of patents and trademarks. Amortization begins once the patent is issued by the appropriate authoritative bodies. In the period in which a patent application is rejected or efforts to pursue the patent are abandoned, all the related accumulated capitalized costs are expensed. Patents and other intangible assets are amortized on a straight-line basis over the useful life of the underlying patent, which is generally 15 years. All amortization expense related to intangible assets is included in general and administrative expenses in the accompanying condensed consolidated statements of operations.

# Long-Lived Asset Impairment

The Company reviews long-lived assets for impairment when events or changes in circumstances ("triggering event") indicate that the carrying value of an asset or group of assets may not be recovered. If a triggering event is determined to have occurred, the carrying value of an asset or group of assets is compared to the future undiscounted cash flows expected to be generated by the asset or group of assets. If the carrying value exceeds the undiscounted cash flows of the asset or group of assets, then an impairment exists, which is measured as the excess of fair value over the asset or asset group's carrying value. Fair value is generally determined using the asset's expected future discounted cash flows or market value, if readily determinable.

# Revenue Recognition

The Company's revenue consists primarily of sales of products from its two revenue-generating operating segments, the biomedical market (LCT) and anti-aging market (LSC). The biomedical market sells primary human cell research products with two product categories, cells and media, which are sold both domestically and internationally. The biomedical market also offers performance of quality control (QC) testing services. No revenue from services was earned during the three and nine months ended September 30, 2022 and 2021.

Prior to January 1, 2022, the anti-aging market sold skincare products through two sales channels: ecommerce and professional. The ecommerce channel sold directly to customers through online orders, while professional sales were primarily to spas, salons, and other skincare providers. As of January 1, 2022, the anti-aging market sells products solely through the ecommerce channel. As such, there was no revenue earned pertaining to the professional channel for skin care during the three and nine months ended September 30, 2022.

The following table presents the Company's revenue disaggregated by segment, product group, and geography (in thousands, except percentages):

### **Biomedical market:**

		Three Months Ended September 30, 2022								Nine Months Ended September 30, 2022							
	Dov	nestic	τ.	nternational		Total evenues	% of Total Revenues		Domestic	τ	ternational	,	Total Revenues	% of Total Revenues			
Biomedical products		nesuc		птегнатіонаі	Re	venues	Revenues	_	Domestic		петнапонаг		Kevenues	Revenues			
Cells	\$	212	\$	73	\$	285	20%	\$	855	\$	357	\$	1,212	24%			
Media		956		199		1,155	80%		3,333		461		3,794	76%			
Total	\$	1,168	\$	272	\$	1,440	100%	\$	4,188	\$	818	\$	5,006	100%			

		Т	hree N	Ionths Ended S	epter	nber 30, 20	021	Nine Months Ended September 30, 2021						
						Total	% of Total						Total	% of Total
	Do	mestic	In	ternational	Re	venues	Revenues		Domestic	Iı	iternational		Revenues	Revenues
Biomedical products														
Cells	\$	191	\$	93	\$	284	19%	\$	542	\$	422	\$	964	22%
Media		1,124		123		1,247	81%		3,036		451		3,487	<u>78</u> %
Total	\$	1,315	\$	216	\$	1,531	100%	\$	3,578	\$	873	\$	4,451	100%

### Anti-aging market:

	 T	hree Months Ended	September 30	,	Nine Months Ended September 30,							
	 20	22	20	021		2022		2021				
	otal enues	% of Total Revenues	Total Revenues	% of Total Revenues		Total evenues	% of Total Revenues	Total Revenues	% of Total Revenues			
Skin care sales channels	 											
Ecommerce	\$ 263	100%	\$ 224	72%	\$	744	100% \$	635	72%			
Professional	_	%	87	28%		_	%	247	28%			
Total	\$ 263	100%	\$ 311	100%	\$	744	100% \$	882	100%			

Contract terms for the unit price, quantity, shipping and payment are governed by sales agreements, invoices or online order forms, which the Company considers to be a customer's contract. The unit price is considered the observable stand-alone selling price for the performance obligation(s) within the arrangements. Any promotional or volume sales discounts are applied evenly to the units sold for purposes of calculating standalone selling price.

The Company recognizes revenue when its customer obtains control of the promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Product sales generally consist of a single performance obligation that the Company satisfies at a point in time (i.e., upon delivery of the product).

For LSC products, ecommerce sales are primarily paid through credit card charges. The anti-aging and biomedical products' standard payment terms for its customers are generally 30 days after the Company satisfies the performance obligation(s).

The Company elects to account for shipping and handling costs as activities to fulfill the promise to transfer the goods to a customer. As a result, no consideration is allocated to shipping and handling costs. Rather, the Company accrues the cost of shipping and handling upon shipment of the product, and all contract revenue (i.e., the transaction price) is recognized at the same time.

# Variable Consideration

The Company records revenue from customers in an amount that reflects the consideration it expects to be entitled to after transferring control of those goods or services to a customer. From time to time, the Company offers sales promotions on its products such as discounts and free product offers. Variable consideration is estimated at contract inception only to the extent that it is probable that a significant reversal of revenue will not occur and is updated at the end of each reporting period as additional information becomes available.

### Contract Balances

The Company records a receivable when it has an unconditional right to receive consideration after a performance obligation is satisfied. As of September 30, 2022 and December 31, 2021, accounts receivable, net, totaled \$427 thousand and \$844 thousand, respectively. During the nine months ended September 30, 2022 and 2021, the Company did not incur material write-offs of its accounts receivable.

# **Practical Expedients**

The Company has elected the practical expedient to not determine whether contracts with customers contain significant financing components. The Company pays commissions on certain sales for its biomedical and anti-aging product markets once the customer payment has been received, which are accrued at the time of sale. The Company generally expenses sales commissions when incurred because the amortization period would be one year or less. These costs are recorded within selling and marketing expenses. In addition, the Company has elected to exclude sales taxes consideration from the determined transaction price.

# Cost of Sales

Cost of sales consists primarily of salaries and benefits associated with employee efforts expended directly on the production of the Company's products as well as related direct materials, general laboratory supplies and an allocation of overhead.

# Research and Development Costs

Research and development costs, which are expensed as incurred, primarily consist of salaries and benefits associated with research and development personnel, overhead and occupancy costs, contract services costs, and amortization of license costs for technology used in research and development with alternative future uses, offset by the research and development tax credit provided by the Australian Taxation Office for qualified expenditures.

# Australian Research and Development Tax Credit

The Company's wholly owned subsidiary, Cyto Therapeutics, conducts various research and development activities on the Company's product candidates in Australia. Under Australian tax law, the Australian Taxation Office provides for a refundable tax credit in the form of a cash refund equal to 43.5% of qualified research and development expenditures, not to exceed established thresholds. The Australian R&D tax incentive program is a self-assessment process and the Australian Government has the right to review the Company's qualifying programs and related expenditures for a period of four years. If such a review were to occur and, as a result of the review and failure of a related appeal, the qualified program and related expenditures were disqualified, the respective research and development refunds could be recalled with penalties and interest.

The refundable tax credit does not depend on the Company's generation of future taxable income or ongoing tax status or position. Accordingly, the credit is not considered an element of income tax accounting under ASC 740 "Income Taxes". The Company uses the grant accounting model by analogy to International Accounting Standards (IAS) 20 to account for the refundable tax credit from the Australian government. The Company recognizes the research and development tax credit as a reduction to research and development expense when there is reasonable assurance that the tax credit will be received, the relevant expenses have been incurred, and the amount can be reliably measured. Accordingly, the Company recognized a reduction of \$80 thousand and \$113 thousand in research and development costs for the nine months periods ended September 30, 2022 and 2021, respectively.

# Stock-Based Compensation

The cost of a stock-based award is measured at the grant date based on the estimated fair value of the award. Stock-based compensation is recognized as expense on a straight-line basis, net of forfeitures, which are recognized as incurred, over the requisite service period of the award. The fair value of stock options is estimated using the Black-Scholes option valuation model, which requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option.

# Fair Value Measurements

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

the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

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

The Company believes that the carrying value of its cash, accounts receivables, accounts payable, accrued liabilities and related party note payable as of September 30, 2022 and December 31, 2021 approximate their fair values because of the short-term nature of those instruments. As of September 30, 2022 and December 31, 2021, the Company had no financial assets or liabilities measured at fair value on a recurring basis.

# Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of stock options and convertible preferred stock. For the three and nine months ended September 30, 2022 and 2021, there was no difference in the number of shares used to calculate basic and diluted shares outstanding.

For the three and nine months ended September 30, 2022 and 2021, the following common stock options and convertible preferred stock were not included in the diluted net loss per share calculation because the effect would be anti-dilutive:

	September	30,
	2022	2021
Options outstanding	6,858,492	5,440,173
Redeemable convertible preferred stock	2,457,143	2,457,143
Non-redeemable convertible preferred stock	3,619,379	3,209,835
Total	12,935,014	11,107,151

### Customer Concentrations

For the nine months ended September 30, 2022 and 2021, one customer accounted for approximately 43% and 38% of consolidated revenues, respectively. As of September 30, 2022 and December 31, 2021, the customer accounted for approximately 35% and 62%, respectively, of accounts receivable, net. No other single customer accounted for more than 10% of revenues for the periods then ended for any segment.

### Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). The ASU introduced a new credit loss methodology, the Current Expected Credit Losses ("CECL") methodology, which requires earlier recognition of credit losses, while also providing additional transparency about credit risk. The CECL methodology utilizes a lifetime "expected credit loss" measurement objective for the recognition of credit losses for loans, held-to maturity debt securities, trade receivables and other receivables measured at amortized cost at the time the financial asset is originated or acquired. Subsequent to the issuance of ASU 2016-13, the FASB issued several additional ASUs to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. In November 2019, the FASB issued an amendment making this ASU effective for fiscal years beginning after December 15, 2022 for smaller reporting companies. The new standard will be effective for the Company on January 1, 2023 or at such earlier time where it is no longer a smaller reporting company. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06"). ASU 2020-06 simplifies the

accounting for convertible debt instruments by reducing the number of accounting models and the number of embedded features that could be recognized separately from the host contract. Consequently, more convertible debt instruments will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. ASU 2020-06 also requires use of the if-converted method in the diluted earnings per share calculation for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years for smaller reporting companies, with early adoption permitted. The new standard will be effective for the Company on January 1, 2024 or at such earlier time where it is no longer a smaller reporting company. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

# Recently Adopted Accounting Pronouncements

In May 2021, the FASB issued ASU No. 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718), and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force) ("ASU 2021-04"), which clarifies and reduces the diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. ASU 2021-04 is effective for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years, with early adoption permitted. The Company adopted ASU 2021-04 on January 1, 2022. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

In November 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832): Disclosure by Business Entities about Government Assistance ("ASU 2021-10"), which improves the transparency of government assistance received by certain business entities by requiring the disclosure of (1) the types of government assistance received; (2) the accounting for such assistance, and (3) the effect of the assistance on the business entity's financial statements. ASU 2021-10 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted. The Company adopted ASU 2021-10 on January 1, 2022. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

### 2. Inventory

The components of inventory are as follows (in thousands):

		mber 30, 022	ember 31, 2021
Raw materials	\$	697	\$ 592
Work in process		553	507
Finished goods		1,129	983
	<u> </u>	2,379	2,082
Less: allowance for excess and obsolete inventory		(595)	(526)
Total current and non-current inventory, net	\$	1,784	\$ 1,556
Inventory, net	\$	1,415	\$ 1,184
Non-current inventory, net		369	372
Total current and non-current inventory, net	\$	1,784	\$ 1,556

# 3. Prepaid and Other Current Assets

The components of prepaid and other current assets are as follows (in thousands):

	Septen	iber 30,	Decer	nber 31,	
	20	22	2021		
Prepaid assets	\$	139	\$	118	
Other current assets		53		17	
Total prepaid and other current assets	\$	192	\$	135	

# 4. Property and Equipment

Property and equipment consist of the following (in thousands):

	-	ember 30, 2022	mber 31, 2021
Machinery and equipment	\$	1,603	\$ 1,610
Computer equipment and software		243	243
Office equipment		104	104
Leasehold improvements		558	549
Construction in progress		_	1
		2,508	2,507
Less: accumulated depreciation and amortization		(2,229)	(2,123)
Property and equipment, net	\$	279	\$ 384

Depreciation and amortization expense for the three months ended September 30, 2022 and 2021 was \$34 thousand and \$41 thousand, respectively. Depreciation and amortization expense for the nine months ended September 30, 2022 and 2021 was \$106 thousand and \$124 thousand, respectively.

# 5. Intangible Assets

Intangible Assets consist of the following (in thousands):

	September 30, 2022			December 31, 2021		
Patents	\$	1,284	\$	1,277		
Less: accumulated amortization		(463)		(403)		
		821		874		
Indefinite life logos and trademarks		75		75		
Intangible assets, net	\$	896	\$	949		

Amortization expense for the three months ended September 30, 2022 and 2021 was \$21 thousand and \$24 thousand, respectively. Amortization expense for the nine months ended September 30, 2022 and 2021 was \$60 thousand and \$71 thousand, respectively.

# 6. Convertible Preferred Stock and Stockholders' Deficit

# Convertible Preferred Stock

As of September 30, 2022 and December 31, 2021, the Company was authorized to issue 20,000,000 shares of preferred stock, \$0.001 par value per share. The Company designated 50 shares of Series D redeemable convertible preferred stock and 10,004,310 shares of Series B, Series G, and Series I-2 non-redeemable convertible preferred stock.

# Non-Redeemable Convertible Preferred Stock

The Company's Series B, Series G, and Series I-2 non-redeemable convertible preferred stock has been classified as equity on the accompanying condensed consolidated balance sheets.

The authorized, issued, and outstanding shares of non-redeemable convertible preferred stock as of September 30, 2022 consist of the following:

	Shares Authorized	Shares Issued and Outstanding	Liquidation Preference		Carry Valu		
	_			(in tho	usands)		
Series B	5,000,000	250,000	\$	468	\$		
Series G	5,000,000	5,000,000		5,000			5
Series I-2	4,310	4,310		4,310			_
Total	10,004,310	5,254,310	\$	9,778	\$		5

The authorized, issued and outstanding shares of non-redeemable convertible preferred stock as of December 31, 2021 consisted of the following:

	Shares Authorized	Shares Issued and Outstanding	Liquidation Preference		Carryin Value	g
				(in thousa	ands)	
Series B	5,000,000	250,000	\$	456	\$	_
Series G	5,000,000	5,000,000		5,000		5
Series I-2	4,310	4,310		4,310		_
Total	10,004,310	5,254,310	\$	9,766	\$	5

# Series D Preferred Stock Redemption

The Company's Series D redeemable convertible preferred stock contains a contingent redemption feature that is not solely within the Company's control. Accordingly, the Series D redeemable convertible preferred stock is classified in temporary equity (outside of permanent equity) on the accompanying consolidated balance sheets.

# Dividends

Holders of the Company's convertible preferred stock are entitled to participating dividends with common stock when and if declared by the Company's board of directors. No dividends have been declared during the nine months ended September 30, 2022.

# Liquidation

Liquidation preference among classes of preferred shares is first with Series D with priority followed by Series G, Series B and Series I-2 on the proceeds from any sale or liquidation of the Company in an amount equal to the purchase price of shares plus (in the case of the Series B) an amount equal to 1% of the Series B original issue price for every two calendar months from February 1, 2008. Following the satisfaction of the liquidation preferences, all shares of common stock participate in any remaining distribution.

### Conversion

The shares of convertible preferred stock are convertible into one share of common stock at any time, at the option of the holder. The conversion rates of the Series B, Series D, and Series I-2 are subject to anti-dilution adjustments whereby, subject to specified exceptions, if the Company issues equity securities or securities convertible into equity at a price below the applicable conversion price of the Series B, Series D, and Series I-2, the conversion price of each such series shall be adjusted downward to equal the price of the new securities. The conversion rate of the Series G is subject to a weighted-average adjustment in the event of the issuance of additional shares of common stock below the conversion price, subject to specified exceptions. The conversion price of the Series I-2 are also subject to certain resets as set forth in the Certificates of Designation, including a reverse stock split.

The following table summarizes the number of shares of common stock into which each share of convertible preferred stock can be converted as of September 30, 2022:

	Co	Initial onversion Price	Current Conversion Price	Conversion Ratio to Common Stock	Common Stock equivalent
Series B	\$	75.00	\$ 0.39	2.5641030	641,026
Series D	\$	37.50	\$ 1.75	57,142.8571	2,457,143
Series G	\$	60.00	\$ 9.70	0.103099	515,495
Series I-2	\$	1.75	\$ 1.75	571.428571	2,462,858

# Common Stock

As of September 30, 2022 and December 31, 2021, the Company was authorized to issue 120,000,000 shares of common stock, \$0.001 par value per share.

# **Equity Incentive Plans**

The Company adopted the 2006 Equity Participation Plan (as amended the "2006 Plan"), which provides for the grant of stock options, restricted stock and other equity-based awards. Awards for up to 100,000 shares may be granted to employees, directors and consultants under this Plan. The options granted under the 2006 Plan may be either qualified or non-qualified options. Options may be granted with different vesting terms and expire no later than 10 years from the date of grant. The 2006 Plan expired on November 16, 2016. Options and other equity-based awards granted prior to the expiration of the 2006 Plan will continue in effect until the option or award is exercised or terminates pursuant to its terms. No new awards may be granted under the 2006 Plan following its expiration.

The Company adopted the 2010 Equity Participation Plan, as amended (the "2010 Plan"), which provides for the grant of stock options, restricted stock and other equity-based awards. Awards for up to 9,700,000 shares may be granted to employees, directors and consultants under the 2010 Plan. The options granted under the 2010 Plan may be either qualified or non-qualified options and the 2010 Plan is set to terminate in March 2030. Options may be granted with different vesting terms and expire no later than 10 years from the date of grant.

# Stock Options

Transactions involving stock options issued to employees, directors and consultants under the 2006 Plan and the 2010 Plan are summarized below. The following tables summarize the Company's stock option activity for the nine months ended September 30, 2022:

	Number of Options	Weighted- Average Exercise	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	5,373,203	\$ 1.42	7.31	\$ 146
Granted	2,338,528	\$ 0.45		
Forfeited or expired	(853,239)	\$ 1.98		
Outstanding at September 30, 2022	6,858,492	\$ 1.02	7.62	\$ _
Vested and expected to vest at September 30, 2022	6,480,137	\$ 1.05	7.52	\$ _
Exercisable at September 30, 2022	4,234,456	\$ 1.38	6.54	\$ _

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes option valuation model. The weighted-average assumptions used in the Black-Scholes option valuation model to determine the fair value of stock options granted for the nine months ended September 30, 2022 and 2021 were as follows:

	Nine Months Ended S	September 30,
	2022	2021
Risk-free interest rate	2.86%	0.89%
Expected stock price volatility	90.29%	83.85%
Expected dividend yield	0%	0%
Expected life of options (in years)	5.71	5.67

Total stock-based compensation expense recorded in the condensed statements of operations is as follows (in thousands):

	Three Months Ended September 30,			Nine	Months End	ded September 30,		
	2	022		2021	2	2022		2021
Cost of sales	\$	1	\$	3	\$	4	\$	18
Research and development		13		7		29		38
Selling and marketing		2		5		6		27
General and administrative		93		103		251		441
Total	\$	109	\$	118	\$	290	\$	524

Unrecognized compensation expense related to stock options as of September 30, 2022 was \$693 thousand, which is expected to be recognized over a weighted-average period of 2.18 years.

# Common Stock Reserved for Future Issuance

As of September 30, 2022, the Company had shares of common stock reserved for future issuance as follows:

Options outstanding	6,858,492
Common stock available for issuance under the 2010 Plan	2,674,566
Redeemable convertible preferred stock	2,457,143
Non-redeemable convertible preferred stock	3,619,379
Total	15,609,580

# 7. Related Party Transactions

Related party lease arrangements

On October 26, 2021, the Company and S Real Estate Holdings, LLC, a related party, entered jointly into a lease agreement with Rehco Holdings, LLC (the "Lease"), for the purpose of establishing a new corporate headquarters, including corporate, R&D, and manufacturing operations. The lease commenced on November 1, 2021 and expires on December 31, 2026 with no options to extend or renew. The lease was personally guaranteed by Dr. Russell Kern, the Company's Executive Vice President and Chief Scientific Officer.

On December 15, 2021, the Company and S Real Estate Holdings LLC entered into a co-tenant agreement, whereby the Company and S Real Estate Holdings LLC agreed to allocate portions of the base rent and variable charges, including insurance, maintenance costs, taxes and operating expenses, between the parties. During the term of the Lease, the Company will be liable for 40% of all costs incurred in connection with the lease, while S Real Estate Holdings LLC will be liable for the remaining 60%.

Related party note payable

As of December 31, 2021, the Company had an unsecured, non-convertible promissory note, with a principal outstanding amount of \$2.7 million (the "Note") and accrued interest of approximately \$300 thousand with Dr. Andrey Semechkin, the Company's Chief Executive Office and Co-Chairman of the Board of Directors. The outstanding principal amount under the Note accrued interest at a rate of 4.5% per annum. The outstanding principal and accrued interest on the Note was due and payable on January 15, 2022 and could be pre-paid without penalty at any time.

On January 13, 2022, to obtain funding for working capital purposes, the Company issued an unsecured, non-convertible promissory note in the principal amount of \$2.9 million (the "Modified Note") to Dr. Semechkin. In exchange, Dr. Semechkin surrendered the Note and provided an additional \$250 thousand to the Company. The Modified Note, including outstanding amounts of principal and accrued interest, was due and payable on March 15, 2022.

On March 1, 2022, the Company and Dr. Andrey Semechkin restructured the Modified Note and agreed to extend the maturity date for an additional six-month period to September 15, 2022. On September 15, 2022, the Company and Dr. Andrey Semechkin extended the Modified Note for an additional six-month period to March 15, 2023. No other terms of the Modified Note were modified. The amendments qualify as a troubled debt restructuring which did not result in a gain as the carrying amount of the debt was less than the total future cash payments of the restructured debt.

# 8. Commitments and Contingencies

# Leases

The Company has three operating leases for real estate in California and Maryland:

- San Diego, California corporate headquarters, including corporate, R&D, and manufacturing operations, with a termination date of December 2026, jointly leased with a related party (refer to Note 7 Related Party Transactions, for further information) ("headquarter lease"). This lease contains no renewal or term extension options;
- San Diego, California supplemental office space adjacent to the Company's corporate headquarters with a termination date of December 2026. This lease contains no renewal or term extension options; and
- Frederick, Maryland mixed laboratory and administrative space with a term date of December 2025. The lease contains one renewal option for an additional three-year term through November 2028. The Company is reasonably certain it will not exercise this renewal option.

The headquarter lease commenced on November 1, 2021 and expires on December 31, 2026. At commencement, base rent due under the lease was approximately \$11 thousand and increases approximately 3.5% per annum over the lease term. The lease is subject to additional variable charges, including insurance, maintenance costs, taxes and operating expenses. Base rent and additional variable charges are shared between the Company and S Real Estate Holdings LLC, a related party, pursuant to a co-tenant agreement between the parties (refer to Note 7 – Related Party Transactions, for further information). In addition, base rent for months two through five of the lease term were abated by 50%.

In November 2021, the Company entered into an operating lease for supplemental office space adjacent to its new corporate headquarters with the same landlord. The lease commenced on December 1, 2021 and expires on December 31, 2026 and is not subject to the co-tenant agreement with S Real Estate Holdings, LLC. At commencement, base rent due under the supplemental office lease was approximately \$4 thousand per month and increases at a fixed amount per annum over the lease term.

The Company's operating leases for real estate are subject to additional variable charges for common area maintenance and other variable costs. Variance costs for the three and nine months ended September 30, 2022 and 2021 were immaterial. All operating lease expense is recognized on a straight-line basis over the lease term. For the three months ended September 30, 2022 and 2021, lease expense totaled \$71 thousand and \$118 thousand, respectively. For the nine months ended September 30, 2022 and 2021, lease expense totaled \$213 thousand and \$355 thousand, respectively. As of September 30, 2022 and December 31, 2021, the Company had no finance leases.

Maturities of lease liabilities are as follows (in thousands):

Years ending December 31,	
2022 (remaining three months)	\$ 82
2023	338
2024	349
2025	360
2026	119
Total minimum lease payments	 1,248
Less: imputed interest	(248)
Total future minimum lease payments	 1,000
Less: operating lease liabilities, current	(219)
Operating lease liabilities, net of current portion	\$ 781

# Licensed patents

The Company had a minimum annual license fee of \$75 thousand payable in two installments per year to Astellas Pharma pursuant to the amended UMass IP license agreement. The patents, along with the license agreement, expired at the end of July 2022. These patents were fully impaired in prior years and therefore the expiration did not result in any impairment for the nine months ended September 30, 2022. The Company does not anticipate any short-term liquidity effects from this obligation as they will no longer be liable for the annual licensing fee.

# 9. Segments

The Company operates the business on the basis of three reporting segments, the parent company and two business units: ISCO – therapeutic market; LCT – biomedical market; LSC – anti-aging market.

The Company does not measure the performance of its segments on any asset-based metrics. Therefore, segment information is presented only for operating loss. Revenues, expenses and operating loss for the three and nine months ended September 30, 2022 and 2021 by reporting segment were as follows (in thousands):

	Three Months Ended September 30,			Nine Months Ended Sept			tember 30,	
		2022		2021		2022		2021
Product sales, net:								
Biomedical market	\$	1,440	\$	1,531	\$	5,006	\$	4,451
Anti-aging market		263		311		744		882
Total product sales, net		1,703		1,842		5,750		5,333
Operating expenses:								
Therapeutic market		561		958		1,794		2,516
Biomedical market		1,011		1,159		3,045		3,320
Anti-aging market		431		348		1,155		1,095
Total operating expenses		2,003		2,465		5,994		6,931
Loss from operations								
Therapeutic market		(561)		(958)		(1,794)		(2,516)
Biomedical market		429		372		1,961		1,131
Anti-aging market		(168)		(37)		(411)		(213)
Total loss from operations	\$	(300)	\$	(623)	\$	(244)	\$	(1,598)

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

The following discussion of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes and other financial information included elsewhere herein. This information should also be read in conjunction with our audited historical consolidated financial statements which are included in our Form 10-K for the fiscal year ended December 31, 2021 ("Form 10-K"). The discussion contains forward-looking statements, such as our plans, expectations and intentions (including those related to clinical trials and business and expense trends), that are based upon current expectations and that involve risks and uncertainties. Our actual results may differ significantly from management's expectations. The factors that could affect these forward-looking statements are discussed in the Risk Factors included in our Form 10-K. This discussion should not be construed to imply that the results discussed herein will necessarily continue into the future, or that any expectations expressed herein will necessarily be indicative of actual operating results in the future. Such discussion represents only the best assessment by our management.

### **Business Overview**

We are a clinical stage biotechnology company devoted to discovering and developing innovative therapies using human parthenogenetic stem cells to treat severe diseases of the central nervous system, joints, and liver. Our lead product candidate, ISC-hpNSC is designed to treat Parkinson's Disease, traumatic brain injury, and ischemic stroke. ISC-hpNSC-based therapy is in phase I clinical trials for Parkinson's disease, while therapies for traumatic brain injury and ischemic stroke are in preclinical stages. We have additional product candidates in development for osteoarthritis and metabolic liver diseases. We currently intend to commercialize our products directly or through collaborations. None of our product candidates have been approved for sale in the United States or elsewhere.

Our products are based on multi-decade experience with human cell culture and a proprietary type of pluripotent stem cells, human parthenogenetic stem cells ("hpSCs"). Our hpSCs are comparable to human embryonic stem cells ("hESCs") in that they have the potential to be differentiated into many different cells in the human body. However, the derivation of hpSCs does not require the use of fertilized eggs or the destruction of viable human embryos and also offers the potential for the creation of immune-matched cells and tissues that are less likely to be rejected following transplantation. Our collection of hpSCs, known as UniStemCell<sup>TM</sup>, currently consists of 15 stem cell lines. We have facilities and manufacturing protocols that comply with the requirements of current Good Manufacturing Practice (cGMP) standards as promulgated by the U.S. Code of Federal Regulations and enforced by the United States Food and Drug Administration ("FDA").

We have generated aggregate product sales revenues from our Biomedical and Anti-aging commercial businesses of \$1.7 million and \$1.8 million for the three months ended September 30, 2022 and 2021, respectively. We have generated aggregate product sales revenues from our Biomedical and Anti-aging commercial businesses of \$5.8 million and \$5.3 million for the nine months ended September 30, 2022 and 2021, respectively. We currently have no revenue generated from our principal operations in the therapeutic market and we do not expect to generate any revenue in this market unless and until we successfully complete clinical product development and obtain regulatory approval for our product candidates.

### COVID-19 Pandemic

The impact of the COVID-19 pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Impacts to our business have included reduced occupancy of portions of our manufacturing facilities, and disruptions or restrictions on our employee's ability to travel to such manufacturing facilities, which have caused minor delays in manufacturing. Our manufacturing facilities continue to operate as they are deemed essential suppliers in accordance with laws applicable to California and Maryland. We have taken precautionary measures to better ensure the health and safety of our workers, including staggering employees' shifts and isolating at-risk employees.

The scope and duration of these delays and disruptions, and the ultimate impacts of COVID-19 on our operations, are currently unknown. We are continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state, or local authorities or that we determine are in the best interests of public health and safety. We cannot predict the effects that such actions, or the impact of COVID-19 on global business operations and economic conditions, may continue to have on our business, strategy, collaborations, or financial and operating results.

Market Opportunity and Growth Strategy

# Therapeutic Market - Clinical Applications of hpSCs for Disease Treatments

With respect to therapeutic research and product candidates, we focus on applications where cell and tissue therapy is already proven but where there is an insufficient supply of safe and functional cells or tissue. We believe that the most promising potential clinical applications of our technology are Parkinson's disease ("PD"), traumatic brain injury ("TBI"), and stroke. Using our proprietary technologies and know-how, we are creating neural stem cells from hpSCs as a potential treatment of PD, TBI, and stroke.

PD: Our most advanced project is the neural stem cell program for the treatment of Parkinson's disease. In 2013, we published in Nature Scientific Reports the basis for our patent on a new method of manufacturing neural stem cells, which is used to produce the clinical-grade cells necessary for future clinical studies and commercialization. In 2014, we completed the majority of the preclinical research, establishing the safety profile of NSC in various animal species, including non-human primates. In June 2016, we published the results of a 12-month pre-clinical non-human primate study, which demonstrated the safety, efficacy and mechanism of action of the ISC-hpNSC®. In 2017, we dosed four patients in our Phase I trial of ISC-hpNSC®, human parthenogenetic stem cell-derived neural stem cells for the treatment of Parkinson's disease. We reported 12-month results from the first cohort and 6-month interim results of the second cohort at the Society for Neuroscience annual meeting (Neuroscience 2018) in November 2018. In April 2019, we announced the completion of subject enrollment, with the 12th subject receiving a transplantation of the highest dose of cells. There have been no safety signals or serious adverse effects seen to date as related to the transplanted ISC-hpNSC® cells.

We announced a successful completion of the dose escalating phase 1 clinical trial in June 2021. In terms of preliminary efficacy, where scores are compared against baseline before transplantation, we observed a potential dose-dependent response with an apparent peak effectiveness at our middle dose. The % OFF-Time, which is the time during the day when levodopa medication is not performing optimally and PD symptoms return, decreased an average 47% from the baseline at 12 months post transplantation in cohort 2. This trend continued through 24 months where the % OFF-Time in the second cohort dropped by 55% from the initial reading. The same was true for % ON-Time without dyskinesia, which is the time during the day when levodopa medication is performing optimally without dyskinesia. The % ON-Time increased an average of 42% above the initial evaluation at 12 months post-transplantation in the second cohort.

Stroke: In August 2014, we announced the launch of a stroke program, evaluating the use of ISC-hpNSC® transplantation for the treatment of ischemic stroke using a rodent model of the disease. The Company has a considerable amount of safety data on ISC-hpNSC® from the Parkinson's disease program and, as there is evidence that transplantation of ISC-hpNSC® may improve patient outcomes as an adjunctive therapeutic strategy in stroke, having a second program that can use this safety dataset is therefore a logical extension. In 2015, the Company together with Tulane University demonstrated that NSC can significantly reduce neurological dysfunction after a stroke in animal models.

TBI: In October 2016, we announced the results of the pre-clinical rodent study, evaluating the use of ISC-hpNSC® transplantation for the treatment of TBI. The study was conducted at the University of South Florida Morsani College of Medicine. We demonstrated that animals receiving injections of ISC-hpNSC® displayed the highest levels of improvements in cognitive performance and motor coordination compared to vehicle control treated animals. In February 2019, we published the results of the pre-clinical study in Theranostics, a prestigious peer-reviewed medical journal. The publication titled, "Human parthenogenetic neural stem cell grafts promote multiple regenerative processes in a traumatic brain injury model," demonstrated that the clinical-grade

neural stem cells used in our Parkinson's disease clinical trial, ISC-hpNSC®, significantly improved TBI-associated motor, neurological, and cognitive deficits without any safety issues

# Anti-Aging Cosmetic Market - Skin Care Products

Our wholly owned subsidiary Lifeline Skin Care, Inc. ("LSC") develops, manufactures and sells anti-aging skin care products based on two core technologies: encapsulated extract derived from hpSC and specially selected targeted small molecules. LSC's products include:

- ProPlus Advanced Defense Complex
- ProPlus Advanced Recovery Complex
- ProPlus Eye Firming Complex
- · ProPlus Neck Firming Complex
- · ProPlus Advanced Aquoues Treatment
- ProPlus Collagen Booster (Advanced Molecular Serum)
- ProPlus Elastin Booster
- · ProPlus Brightening Toner

LSC's products are regulated as cosmetics. LSC's products are sold domestically through a branded website, Amazon, and ecommerce partners.

### Biomedical Market - Primary Human Cell Research Products

Our wholly owned subsidiary Lifeline Cell Technology, LLC ("LCT") develops, manufactures and commercializes approximately 200 human cell culture products, including frozen human "primary" cells and reagents (called "media"), which are needed to grow, maintain, and differentiate the cells. LCT's scientists have used a standardized, methodical, scientific approach to basal medium optimization to systematically produce optimized products designed to culture specific human cell types and to elicit specific cellular behaviors. These techniques can also be used to produce products that do not contain non-human animal proteins, a feature desirable to the research and therapeutic markets. Each LCT cell product is quality tested for the expression of specific markers (to assure the cells are the correct type), proliferation rate, viability, morphology and absence of pathogens. Each cell system also contains associated donor information and all informed consent requirements are strictly followed. LCT's research products are marketed and sold by its internal sales force, OEM partners and LCT brand distributors in Europe and Asia.

# **Results of Operations**

# Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,						
		2022		2021	\$ Change	% Change	
				(dollar in tho	usands)		
Product sales, net	\$	1,703	\$	1,842	\$ (139)	-8%	
Cost of sales		690		814	(124)	-15%	
As a % of product sales, net		41%		44%			
Research and development		147		165	(18)	-11%	
Selling and marketing		358		352	6	2%	
General and administrative		808		1,134	(326)	-29%	
Other income (expense), net		(43)		458	(501)	-109%	
Net loss	\$	(343)	\$	(165)	\$ (178)	108%	
As a % of product sales, net		-20%		-9%			

### Product sales, net

Product sales for the three months ended September 30, 2022 were \$1.7 million compared to \$1.8 million for the three months ended September 30, 2021. The decrease of \$139 thousand, or 8%, was primarily attributable to a decrease of \$212 thousand in our OEM Cells and Media product sales offset by increases of \$122 thousand in non-OEM Cells and Media product sales in our Biomedical market segment. This decrease in OEM product sales is attributed to timing differences in restocking orders received for OEM customers, wherein less restocking orders were received for the three-month period ended September 30, 2022, compared to the same period in 2021. The increase in non-OEM product sales is attributed to an increase in demand from government researchers as they establish or re-establish operations in-person after the COVID 19 shutdown for the three months ended September 30, 2022 as compared to the same period 2021. There was an additional decrease in our skin care product sales of approximately \$49 thousand as a result of decreased sales from the discontinuation of the professional line of anti-aging products, resulting in only one product line and less demand.

### Cost of sales

Cost of sales for the three months ended September 30, 2022 was \$690 thousand, compared to \$814 thousand for the three months ended September 30, 2021. The decrease of \$124 thousand, or 15%, was primarily attributable to a \$25 thousand decrease in costs as a result of a decrease in product sales and a \$113 thousand increase in favorable manufacturing variances driven by higher Cell product rather than Media sales. These decreases were partially offset by approximately \$13 thousand for inventory related transactions.

Profit margins have increased approximately 3 percentage points for the three months ended September 30, 2022, as compared to the three months ended September 30, 2021. This is largely a result of cost saving measures, such as bulk purchases, taken to address rising raw materials and labor-related costs as well as sales mix differences.

Cost of sales consists primarily of salaries and benefits associated with employee efforts expended directly on the production of the Company's products, as well as related direct materials, general laboratory supplies and an allocation of overhead. We aim to continue to refine our manufacturing processes and supply chain management to improve the cost of sales as a percentage of revenue for both LCT and LSC.

# Research and development income

Research and development expense for the three months ended September 30, 2022 was \$147 thousand, compared to an expense of \$165 thousand for the three months ended September 30, 2021. The decrease of \$18 thousand, or 11%, was as a result of a decrease of approximately \$19 thousand in other patent related cost quarter over quarter. There was also a \$43 thousand net decrease related to supplies, facilities and licensing, which was offset by increased personnel and stock compensation costs including consultant costs of approximately \$44 thousand.

Our research and development efforts are primarily focused on the development of treatments for Parkinson's disease, traumatic brain injury, and stroke. These projects are long-term investments that involve developing both new stem cell lines and new differentiation techniques that can provide higher purity populations of functional cells. Research and development expenses are expensed as incurred and are accounted for on a project-by-project basis. However, much of our research has potential applicability to each of our projects.

### Selling and marketing expenses

Selling and marketing expenses for the three months ended September 30, 2022 were \$358 thousand, compared to \$352 thousand for the three months ended September 30, 2021. The increase of \$6 thousand, or 2%, was primarily attributable to an increase in advertising expenses.

Our sales and marketing expenses consist primarily of employee-related expenses including salaries, bonuses, benefits, and share-based compensation for our Biomedical and Anti-aging cosmetic businesses. Other significant costs include facility costs not otherwise included in or allocated to other departments as well as marketing material costs, permits and licenses for ecommerce, and other advertising type expenses.

# General and administrative expenses

General and administrative expenses for the three months ended September 30, 2022 were \$808 thousand, compared to \$1,134 thousand for the three months ended September 30, 2021. The decrease of \$326 thousand, or 29%, was primarily attributable to a

decrease of \$250 thousand related to a patent impairment charge taken in FY 2021. The remainder pertained to decreases in personnel-related costs as well as legal, audit, and other general fees.

Our general and administrative expenses consist primarily of employee-related expenses including salaries, bonuses, benefits, and share-based compensation. Other significant costs include facility costs not otherwise included in or allocated to other departments, legal fees not relating to patents and corporate matters, and fees for accounting and consulting services.

Other income (expense), net

Other expense, net for the three months ended September 30, 2022 was \$43 thousand, compared to other income, net of \$458 thousand for the three months ended September 30, 2022. The decrease was primarily attributable to the forgiveness of the PPP loan in the prior period.

# Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

		Nine Months Ended September 30,					
	2	2022		2021	\$ C	hange	% Change
				(dollar in tl	nousands)		
Product sales, net	\$	5,750	\$	5,333	\$	417	8%
Cost of sales		2,133		2,200		(67)	-3%
As a % of product sales, net		37%		41%			
Research and development		367		492		(125)	-25%
Selling and marketing		982		1,049		(67)	-6%
General and administrative		2,512		3,190		(678)	-21%
Other income (expense), net		(110)		1,050		(1,160)	-110%
Net loss	\$	(354)	\$	(548)	\$	194	-35%
As a % of product sales, net		-6%		-10%			

Product sales, net

Product sales for the nine months ended September 30, 2022 and 2021 were \$5.8 million and \$5.3 million, respectively. The increase of \$417 thousand, or 8%, was primarily attributable to an increase in our OEM and non-OEM Media product sales in our Biomedical market segment of \$346 thousand, coupled with a net increase in OEM and non-OEM Cell product sales of \$209 thousand. The increase in OEM and non-OEM Media and Cell product sales is attributed to an increase in demand from private customers and government researchers as they establish or re-establish operations in-person after the COVID 19 shutdown for the nine months ended September 30, 2022 as compared to the same period 2021. The increase is partially offset by approximately \$138 thousand decrease in sales related to the professional line of anti-aging products being discontinued (resulting in only one product line and less demand) for the nine months ended September 30, 2022 as compared to 2021.

Our media product sales have recovered, in part as a result of increased demand from our largest original equipment manufacturer customers. For the year ending 2022, we estimate domestic biomedical product sales will exceed or be comparable to the year ended 2021. International product sales in our biomedical market are down from 2021.

Our anti-aging market segment includes skin care products that are distributed through various ecommerce channels (and were also previously distributed through a professional channel). Our anti-aging product sales have experienced a significant decline in customer demand for the nine months ended September 30, 2022, as compared to 2021, as a result of COVID-19's impact on the operations of retail and professional medical offices, which began to be adversely impacted largely in the second quarter of 2021 and have not since recovered.

Cost of sales

Cost of sales for the nine months ended September 30, 2022 and 2021 was \$2.1 million and \$2.2 million, respectively. The decrease of \$67 thousand, or 3%, was primarily attributable to a \$386 thousand increase in favorable manufacturing variances and absorption due to increased sales volume of cell rather than media products. This is offset by an increase in costs of \$237 thousand as a result of an increase in product sales (including shipping) and \$82 thousand from inventory purchases.

Profit margins increased by approximately 4 percentage points for the nine months ended September 30, 2022 as compared to 2021. This is largely a result of cost saving measures, such as bulk purchases, taken to address rising raw materials and labor-related costs and supply chain obstacles as well as sales mix differences.

We may modify or expand certain product promotions and discounts through the end of 2022 as we continue to assess the ongoing impact of COVID-19 on our business, which may have an adverse impact on our profit margins.

Cost of sales consists primarily of salaries and benefits associated with employee efforts expended directly on the production of the Company's products, as well as related direct materials, general laboratory supplies and an allocation of overhead. We aim to continue to refine our manufacturing processes and supply chain management to improve the cost of sales as a percentage of revenue for both LCT and LSC.

# Research and development expenses

Research and development expenses for the nine months ended September 30, 2022 and 2021 were \$367 thousand and \$492 thousand, respectively. The decrease of \$125 thousand, or 25%, was primarily attributable to an \$85 thousand decrease in allocated building-related expenses, a \$40 thousand decrease in consulting and personnel-related costs as a result of headcount reductions following the conclusion of the active phase of our Phase 1 clinical study, and a \$41 thousand decrease in materials, supplies and licensing related expenses. These decreases were partially offset by a \$42 thousand decrease in our Australian research and development tax credit related to qualifiable expenditures from our research and development activities of our Australian subsidiary, Cyto Therapeutics.

Our research and development efforts are primarily focused on the development of treatments for Parkinson's disease, traumatic brain injury and stroke. These projects are long-term investments that involve developing both new stem cell lines and new differentiation techniques that can provide higher purity populations of functional cells. Research and development expenses are expensed as incurred, including allocations for facilities and depreciation, and are accounted for on a project-by-project basis. However, much of our research has potential applicability to each of our projects.

# Selling and marketing expenses

Selling and marketing expenses for the nine months ended September 30, 2022 were \$982 thousand, compared to \$1,049 thousand for the nine months ended September 30, 2021. The decrease of \$67 thousand, or 6%, was predominately attributable to decreases in personnel-related costs, including temporary services and stock-based compensation, of \$74 thousand and building and facilities related expenses as a result of headcount reductions of \$20 thousand. These decreases were partially offset by approximately \$27 thousand in increased advertising expense for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021.

Our sales and marketing expenses consist primarily of employee-related expenses including salaries, bonuses, benefits, and share-based compensation for our Biomedical and Anti-aging cosmetic businesses. Other significant costs include facility costs not otherwise included in or allocated to other departments as well as marketing material costs, permits and licenses for ecommerce, and other advertising type expenses.

# General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2022 and 2021 were \$2.5 million and \$3.2 million, respectively. The decrease of \$678 thousand, or 21%, was primarily attributable to a decrease of \$250 thousand related to a patent impairment charge taken in FY 2021. The remainder of the decrease pertained to decreases in personnel-related costs as well as legal, audit, and other general fees. These decreases were partially offset by a \$108 thousand increase in consultant and logistic related costs for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021.

Our general and administrative expenses consist primarily of employee-related expenses including salaries, bonuses, benefits and share-based compensation. Other significant costs include facility costs not otherwise included in or allocated to other departments, legal fees not relating to patents and corporate matters, and fees for accounting and consulting services.

# Other income (expense), net

Other expense, net, for the nine months ended September 30, 2022 was \$110 thousand, compared to other income, net of \$1,050 thousand for the nine months ended September 30, 2021. The decrease was primarily attributable to a gain, recognized in 2021, on the forgiveness of debt related to our First and Second Draw Loan under the PPP in the comparative period.

# Liquidity and Capital Resources

The Company enters into contracts in the normal course of business with various third-party consultants and contract research organizations ("CRO") for preclinical research, clinical trials and manufacturing activities. These contracts generally provide for termination upon notice. Actual expenses associated with these arrangements may be higher or lower due to various reasons, including but not limited to, progress of our development products, enrollment in clinical trials, and product and personnel delays due to COVID. Other short-term and long terms commitments that would affect liquidity include lease obligations as well as related party debt repayments.

As of September 30, 2022, we had an accumulated deficit of approximately \$110.4 million and have, on an annual basis, incurred net losses and negative operating cash flows since inception. Substantially all of our operating losses have resulted from the funding of our research and development programs and general and administrative expenses associated with our operations. We incurred net losses of \$354 thousand and \$548 thousand for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had cash of approximately \$666 thousand, compared to \$171 thousand as of December 31, 2021. Our primary use of cash is to continue to fund our research and development programs while maintaining and growing our revenue generating businesses.

### Licensed patents

The Company had a minimum annual license fee of \$75 thousand payable in two installments per year to Astellas Pharma pursuant to the amended UMass IP license agreement. The patents, along with the license agreement, expired at the end of July 2022. These patents were fully impaired in prior years and therefore the expiration did not result in any additional impairment for the nine months ended September 30, 2022. The Company does not anticipate any short-term liquidity effects from this obligation as we will no longer be liable for the annual licensing fee.

### Cash Flows

# Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table provides information regarding our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,			
	20:	22		2021
Net cash provided by (used in) operating activities	\$	253	\$	(981)
Net cash used in investing activities		(8)		(27)
Net cash provided by financing activities		250		824
Net increase in cash	\$	495	\$	(184)

# Operating Cash Flows

For the nine months ended September 30, 2022, our largest source of operating cash is cash collections from our LCT and LSC customers. We did not generate positive cash flows from operating activities for the nine months ended September 30, 2021.

For the nine months ended September 30, 2022, net cash provided by operating activities was \$253 thousand, resulting primarily from our net loss of \$354 thousand and net changes in operating assets and liabilities of \$51 thousand, consisting primarily of decreases in accounts payable of \$130 thousand and operating lease liabilities of \$129 thousand as well as increases in account liabilities of \$71 thousand, inventory, net of \$228 thousand and prepaid expenses and other current assets of \$57 thousand. These are offset by decreases in accounts receivable of \$417 thousand and deposits of \$5 thousand. The net operating decrease was offset by net noncash adjustments of \$658 thousand, pertaining to stock-based compensation and other non-cash expenses.

For the nine months ended September 30, 2021, net cash used in operating activities was \$981 thousand, resulting primarily from our net loss of \$548 thousand and net changes in operating assets and liabilities of \$571 thousand, partially offset by net non-cash adjustments of \$138 thousand.

Investing Cash Flows

Net cash used in investing activities for the nine months ended September 30, 2022 was \$8 thousand, compared to \$27 thousand for the nine months ended September 30, 2021. The decrease was attributable to a decrease in payments for patent licenses as well as decreased purchases of property and equipment year-over-year.

# Financing Cash Flows

Net cash provided by financing activities for the nine months ended September 30, 2022 was \$250 thousand, compared to \$824 thousand for the nine months ended September 30, 2021. The decrease was attributable to proceeds from a note payable from a related party of \$250 thousand in the current year, compared to proceeds from a note payable from a related party of \$350 thousand and proceeds of \$474 thousand from our Second Draw Loan under the Paycheck Protection Program in the prior year.

# **Funding Requirements**

Management continues to evaluate various financing sources and options to raise working capital to help fund our current research and development programs and operations. We will need to obtain significant additional capital from equity and/or debt financings, license arrangements, grants and/or collaborative research arrangements to sustain our operations and develop products. Unless we obtain additional financing, we do not have sufficient cash on hand to sustain our operations at least through one year after the issuance date. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for capital needs;
- the extent that revenues from sales of LSC and LCT products cover the related costs and provide capital;
- · scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs and our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with preclinical development and clinical trials;
- the extent to which third party interest in Company's research and commercial products can be realized through effective partnerships;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the number and type of product candidates that we pursue; and
- the development of major public health concerns, including COVID-19 or other pandemics arising globally, and the current and future impact that such concerns may have on our operations and funding requirements.

Our failure to raise capital or enter into applicable arrangements when needed would have a negative impact on our financial condition. Additional debt financing may be expensive and require us to pledge all or a substantial portion of its assets. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of its technologies, product candidates or products that we would otherwise seek to develop and commercialize on its own. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of its product initiatives.

We currently have no revenue generated from our principal operations in therapeutic and clinical product development through research and development efforts. There can be no assurance that we will be successful in maintaining our normal operating cash flow and obtaining additional funds and that the timing of our capital raising or future financing will result in cash flow sufficient to sustain our operations at least through one year after the issuance date.

Based on the factors above, there is substantial doubt about our ability to continue as a going concern. The consolidated financial statements were prepared assuming that we will continue to operate as a going concern. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. Management's plans in regard to these matters are focused on managing our cash flow, the proper timing of our capital expenditures, and raising additional capital or financing in the future.

### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America and the rules and regulations of the Securities and Exchange Commission. The preparation of these condensed consolidated financial statements requires us to make judgements and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statement, and the reported amounts of revenues, costs and expenses during the reporting periods.

Our estimates are based on our historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and amount of expense recognized that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We evaluate our estimates and assumptions on an ongoing basis. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of the change in estimates.

There have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2022 from those disclosed in "Part II – Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K.

## Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

### **Contractual Obligations and Commitments**

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business during the nine months ended September 30, 2022 from those disclosed in "Part II - Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K.

# Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information required under this item.

# Item 4. Controls and Procedures

### Disclosure Controls and Procedures

# Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(e) and 15d-15(e) under the Exchange Act, the Company, with the participation of management, including our Chief Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in such rules) as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Principal Financial Officer concluded that, at September 30, 2022, our disclosure controls and procedures were effective.

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

Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

# Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls during the nine months ended September 30, 2022 that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

# PART II – OTHER INFORMATION

# Item 1. Legal Proceedings

None.

# Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in "Part I-Item IA. Risk Factors" included in our Annual Report on Form IO-K for the year ended December IO-K for the SEC on March IO-K for the year ended December IO-K for the year

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

None.

# Item 3. Defaults Upon Senior Securities

None.

# Item 4. Mine Safety Disclosures

Not applicable.

# Item 5. Other Information

None.

# Item 6. Exhibits

# Exhibit Index

Exhibit	Description
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.4 of the Registrant's Form 10-SB filed on April 4, 2006).
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Preliminary Information Statement on Form 14C filed on December 29, 2006).
3.3	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on June 4, 2012).
3.4	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on May 14, 2014).
3.5	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on July 28, 2015).
3.6	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on May 19, 2016).
3.7	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on May 6, 2011).
4.1	Form of Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Form 10-KSB filed on April 9, 2007).
4.2	Certification of Designation of Series B Preferred Stock (incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed on May 12, 2008).
4.3	Certification of Designation of Series D Preferred Stock (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on January 5, 2009).
4.4	Certificate of Designation of Series GPreferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on March 14, 2012).
4.5	Certificate of Preferences, Rights and Limitations of Series I-2 Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 of the Registrant's Form 8-K filed on March 10, 2016).
10.1	Form of Note issued on September 15, 2022 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed September 16, 2022)
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1*	Section 1350 Certification of Chief Executive Officer.
32.2*	Section 1350 Certification of Chief Financial Officer.
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)
* Filed herew	ith.

\* Filed herewith.

# SIGNATURES

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

# INTERNATIONAL STEM CELL CORPORATION

Dated: November 14, 2022

By: /s/ ANDREY SEMECHKIN

Name: Andrey Semechkin

Title: Chief Executive Officer
(Principal Executive Officer)

By: /s/ RUSSELL KERN

Name: Russell Kern

Title: EVP and Chief Scientific Officer (Principal Financial Officer)

# CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

Date: November 14, 2022

By: /s/ Andrey Semechkin
Andrey Semechkin
Chief Executive Officer
(Principal Executive Officer)

# CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

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

Date: November 14, 2022

By: /s/ Russell Kern
Russell Kern
EVP and Chief Scientific Officer
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of International Stem Cell Corporation (the "Company") for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrey Semechkin, Chief Executive Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

By: /s/ Andrey Semechkin
Andrey Semechkin
Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Quarterly Report on Form 10-Q of International Stem Cell Corporation (the "Company") for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Russell Kern, EVP, and Chief Scientific Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

By: /s/ Russell Kem
Russell Kem

EVP and Chief Scientific Officer (Principal Financial Officer)