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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

Or

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

For the transition period from to

Commission File Number: 001-34899

Pulse Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware		**46-5696597**
(State or other jurisdiction of incorporation or organization)		**(I.R.S. Employer Identification No.)**
3957 Point Eden Way Hayward, CA		**94545**
(Address of principal executive offices)		**(Zip Code)**

(510) 906-4600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**PLSE**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 ☐

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

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

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

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

The number of shares outstanding of the registrant's common stock as of July 31, 2022: 37,125,947

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"Pulse Biosciences," the Pulse logos and other trademarks or service marks that we use in connection with the operation of our business appearing in this quarterly report on Form 10-Q (this "Quarterly Report"), including CellFX, CellFX CloudConnect, CellFX Marketplace, Nano-pulse Stimulation, and NPS, are the property of Pulse Biosciences, Inc. Solely for your convenience, some of our trademarks and trade names referred to in this Quarterly Report are listed without the ® and TM symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks and trade names. Also, this Quarterly Report may contain additional trade names, trademarks or service marks of others, which are the property of their respective owners. We do not intend our use or display of any other company's trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any of these other companies.

Unless expressly indicated or the context requires otherwise, the terms "Pulse," "Company," "we," "us," and "our," in this document refer to Pulse Biosciences, Inc., a Delaware corporation, and, where appropriate, its wholly owned subsidiaries.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

PULSE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)
(Unaudited)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,798	$ 28,614
Accounts receivable	8	61
Inventory	7,871	5,824
Prepaid expenses and other current assets	1,062	2,131
Total current assets	23,739	36,630
Property and equipment, net	2,386	2,462
Intangible assets, net	2,883	3,216
Goodwill	2,791	2,791
Right-of-use assets	8,433	8,785
Other assets	365	365
Total assets	$ 40,597	$ 54,249
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,948	$ 2,904
Accrued expenses	4,757	4,389
Deferred revenue	32	16
Lease liability, current	827	774
Note payable, current	—	436
Total current liabilities	7,564	8,519
Lease liability, less current	9,618	10,040
Total liabilities	17,182	18,559
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized – 50,000 shares; no shares issued and outstanding	—	—
Common stock, $0.001 par value: authorized – 500,000 shares; issued and outstanding – 37,126 shares and 29,716 shares at June 30, 2022 and December 31, 2021, respectively	37	29
Additional paid-in capital	290,847	271,861
Accumulated other comprehensive loss	—	—
Accumulated deficit	(267,469)	(236,200)
Total stockholders' equity	23,415	35,690
Total liabilities and stockholders' equity	$ 40,597	$ 54,249

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)
(Unaudited)

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2022	2021	2022	2021
Revenues:				
Product revenues	$ 265	$ —	$ 709	$ —
Total revenues	265	—	709	—
Cost and expenses:				
Cost of revenues	1,344	—	2,253	—
Research and development	5,458	7,459	12,227	16,522
Sales and marketing	3,690	3,147	9,231	7,293
General and administrative	3,787	4,200	8,285	9,516
Total cost and expenses	14,279	14,806	31,996	33,331
Loss from operations	(14,014)	(14,806)	(31,287)	(33,331)
Other income (expense):				
Interest income (expense), net	18	(517)	18	(631)
Total other income (expense)	18	(517)	18	(631)
Net loss	(13,996)	(15,323)	(31,269)	(33,962)
Other comprehensive gain (loss):				
Unrealized gain on available-for-sale securities	—	—	—	1
Comprehensive loss	$ (13,996)	$ (15,323)	$ (31,269)	$ (33,961)
Net loss per share:				
Basic and diluted net loss per share	$ (0.44)	$ (0.58)	$ (1.02)	$ (1.29)
Weighted average shares used to compute net loss per common share — basic and diluted	31,492	26,477	30,623	26,276

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six-Month Periods Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (31,269)	$ (33,962)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	347	229
Amortization of intangible assets	333	333
Stock-based compensation	3,720	9,413
Net premium amortization and discount on available-for-sale securities	—	13
Changes in operating assets and liabilities:		
Accounts receivable	53	—
Inventory	(2,047)	(2,691)
Prepaid expenses and other current assets	1,112	(2,454)
Other receivables	(30)	23
Right-of-use assets	352	319
Accounts payable	(931)	1,041
Accrued expenses	296	(754)
Deferred revenue	16	—
Lease liabilities	(369)	(192)
Accrued interest on note payable	1	629
Net cash used in operating activities	(28,416)	(28,053)
Cash flows from investing activities:		
Purchases of property and equipment	(298)	(146)
Maturities of investments	—	8,000
Net cash provided by (used in) investing activities	(298)	7,854
Cash flows from financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	372	421
Proceeds from exercises of warrants	—	4,217
Proceeds from exercises of stock options	—	678
Proceeds from issuance of common stock	14,963	48,348
Proceeds from issuance of related party note	—	1,730
Tax payments related to shares withheld for vested restricted stock units	—	(232)
Payments made on insurance loan agreement	(437)	—
Net cash provided by financing activities	14,898	55,162
Net increase (decrease) in cash and cash equivalents	(13,816)	34,963
Cash and cash equivalents at beginning of period	28,614	12,463
Cash and cash equivalents at end of period	$ 14,798	$ 47,426
Supplemental disclosure of noncash investing and financing activities:		
Equipment purchases included in accounts payable and accrued expenses	$ (27)	$ 65
Change in unrealized gains on available-for-sale securities	—	1
Accrued interest settled via issuance of common stock from private placement equity offering	—	629
Related party other receivable from issuance of common stock from private placement equity offering	—	8,371
Other receivable from issuance of common stock	13	25
Issuance costs for rights offering in accounts payable and accrued expenses	(74)	—

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, March 31, 2022	29,802	$ 29	$ 274,240	$ —	$ (253,473)	$ 20,796
Issuance of shares in Rights Offering, net of issuance costs of $111	7,317	7	14,882	—	—	14,889
Issuance of common stock pursuant to warrant exercise	7	1	12	—	—	13
Stock-based compensation expense	—	—	1,713	—	—	1,713
Net loss	—	—	—	—	(13,996)	(13,996)
Balance, June 30, 2022	37,126	$ 37	$ 290,847	$ —	$ (267,469)	$ 23,415

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2021	29,716	$ 29	$ 271,861	$ —	$ (236,200)	$ 35,690
Issuance of shares in Rights Offering, net of issuance costs of $111	7,317	7	14,882	—	—	14,889
Issuance of common stock under employee stock purchase plan	86	—	372	—	—	372
Issuance of common stock pursuant to warrant exercise	7	1	12	—	—	13
Stock-based compensation expense	—	—	3,720	—	—	3,720
Net loss	—	—	—	—	(31,269)	(31,269)
Balance, June 30, 2022	37,126	$ 37	$ 290,847	$ —	$ (267,469)	$ 23,415

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, March 31, 2021	26,401	$ 26	$ 211,550	$ —	$ (191,179)	$ 20,397
Issuance of common stock as part of debt extinguishment and private investment, net of issuance costs of $59	3,049	3	49,938	—	—	49,941
Issuance of common stock as part of ATM offering	131	—	2,469	—	—	2,469
Issuance of common stock upon exercise of stock options	5	—	59	—	—	59
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	22	—	(232)	—	—	(232)
Adjustment to shares issued under employee stock purchase plan	(2)	—	(9)	—	—	(9)
Stock-based compensation expense	—	—	2,448	—	—	2,448
Net loss	—	—	—	—	(15,323)	(15,323)
Balance, June 30, 2021	29,606	$ 29	$ 266,223	$ —	$ (206,502)	$ 59,750

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance, December 31, 2020	25,550	$ 25	$ 195,410	$ (1)	$ (172,540)	$ 22,894
Issuance of common stock as part of debt extinguishment and private investment, net of issuance costs of $59	3,049	3	49,938	—	—	49,941
Issuance of common stock upon exercise of warrants	585	1	3,333	—	—	3,334
Issuance of common stock as part of ATM offering	288	—	7,432	—	—	7,432
Issuance of common stock upon exercise of stock options	45	—	508	—	—	508
Issuance of common stock under employee stock purchase plan	67	—	421	—	—	421
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	22	—	(232)	—	—	(232)
Stock-based compensation expense	—	—	9,413	—	—	9,413
Unrealized gain on available-for-sale securities	—	—	—	1	—	1
Net loss	—	—	—	—	(33,962)	(33,962)
Balance, June 30, 2021	29,606	$ 29	$ 266,223	$ —	$ (206,502)	$ 59,750

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of the Business

Pulse Biosciences, Inc. is a novel bioelectric medicine company committed to health innovation using an entirely new and proprietary energy modality. The Company's CellFX System is the first commercial product to harness the distinctive advantages of the Company's proprietary NPS technology. The CellFX System delivers nanosecond duration pulses of electrical energy, each less than a millionth of a second long, to non-thermally clear targeted cells while sparing adjacent non-cellular tissue, to treat a variety of medical conditions for which an optimal solution remains unfulfilled.

In February 2021, the Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for the CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin. In January 2021, the Company received CE marking approval for the CellFX System, which allows for marketing of the system in the EU and, in June 2021, the Company received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada. The CE mark and Health Canada approvals allow for use of the CellFX System in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts. The Company will continue to pursue specific indications for the CellFX System in the United States similar to the regulatory clearances already received in Europe and Canada. This will require additional 510(k) submissions for each subsequent indication, and will likely be based on comparative clinical data. In December 2021, the Company submitted a 510(k) to add the treatment of SH to the CellFX System's indications for use in the United States. In February 2022 the Company received an Additional Information ("AI") letter from the FDA in response to the 510(k) submitted. In the AI letter, the FDA stated it did not believe the Company provided sufficient clinical evidence at this time to support the expanded indication for use, and that the Company had not met the primary endpoints of the SH FDA-approved IDE study. The Company met with the FDA at the end of April 2022 to gain clarification regarding the AI letter and to discuss the appropriate next steps. Following the meeting and at the FDA's request, the Company provided additional analysis of the sebaceous hyperplasia comparative clinical data. The Company met with the FDA again in June 2022 to discuss the data. Following this meeting, the FDA requested further data which was provided in July 2022. The Company is expecting feedback from the FDA on the most recent data provided. The Company expects to continue to collaborate with the FDA to formally respond to the AI letter. Separately, in August 2022, the Company received 510(k) clearance from the FDA for expanded energy settings for use with the family of CellFX System treatment tips in dermatology. The expanded energy settings enable clinicians in the U.S. to provide more customized energy delivery specific to individual lesions.

In February 2021, the Company initiated controlled launch programs (Note 9) in the United States and the European Union and in June 2021 the Company initiated a controlled launch program in Canada (collectively, our "Controlled Launch"). In August 2021, the Company began to convert Controlled Launch program participants into sales agreements, thereby triggering revenue recognition.

On March 31, 2022, the Company initiated a plan to reduce its operating expenses, preserve financial resources, and focus its sales and marketing efforts on increasing utilization of CellFX Systems. The Company's Board of Directors approved changes to the Company's commercial leadership, restructuring of its commercial field organization and reductions in other personnel and expenses across the Company. The Company announced a reduction in force effective as of March 31, 2022. See Note 13 for additional details.

The Company was incorporated in Nevada on May 19, 2014. On June 18, 2018, the Company reincorporated from the State of Nevada to the State of Delaware. The Company is located in Hayward, California.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital. The Company does not currently have any cash flows from operations. It has recently commenced revenue-generating operations and will need to raise additional capital to finance its operations. However, there can be no assurances that the Company will be able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund its operating requirements.

2. Summary of Significant Accounting Policies

Going Concern

As of June 30, 2022, the Company had an accumulated deficit of $267.5 million, cash outflows from operations of $28.4 million for the six months then ended, cash and cash equivalents of $14.8 million and a net loss of $31.3 million. The Company has recently begun to generate revenue from product sales, but anticipates net losses for the next several years or until it can generate substantial product revenue and achieve profitability. Based on the Company's current operating plan, the Company has determined that, with its current financial resources, the Company would be able to operate into the fourth quarter of 2022. As the Company's operating plan does not allow the Company to operate for a period of twelve months from the date the condensed consolidated financial statements are issued without additional financing, based on the Accounting Standards Codification ("ASC") 205-40, *Presentation of Financial Statements – Going Concern*, the Company is required to disclose that substantial doubt regarding the Company's ability to continue as a going concern exists. This evaluation initially cannot take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued. To continue to fund the operations of the Company beyond this time period, management has developed plans, which primarily consist of raising additional capital through some combination of public or private equity offerings, debt financings, the Company's at-the-market equity offering program, and/or potential new collaborations. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that management of the Company will be able to obtain financing or enter into a collaboration on terms acceptable to the Company. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared on a basis consistent with the Company's December 31, 2021 audited Consolidated Financial Statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth herein. The condensed consolidated financial statements have been prepared in accordance with the applicable rules and regulations of the Securities and Exchange Commission (the "SEC") and, as permitted by such rules and regulations, omit certain information and footnote disclosures necessary to present the financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The condensed consolidated balance sheet as of December 31, 2021 was derived from the audited consolidated financial statements as of that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. The results of operations for the three-month and six-month periods ended June 30, 2022, are not necessarily indicative of the results to be expected for the entire year or any future periods.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the financial statements of Pulse Biosciences, Inc. and its wholly-owned subsidiaries. Intercompany balances and transactions, if any, have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the Financial Statements and accompanying notes to the condensed consolidated financial statements. Estimates include, but are not limited to, the valuation of cash equivalents, the valuation and recognition of share-based compensation, inventory valuation, warranty obligations, and the useful lives assigned to long-lived assets. The Company evaluates its estimates and assumptions based on historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ materially from these estimates.

Significant Accounting Policies

The Company's significant accounting policies are described in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. The Company continually evaluates the accounting policies and estimates used in preparing the consolidated financial statements. There have been no material changes to the Company's significant accounting policies during the six-month period ended June 30, 2022, as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Valuation of Inventory

Inventory is stated at lower of cost or net realizable value. The Company establishes the inventory basis by determining the cost based on standard costs approximating the purchase costs on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of the Company's business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of the Company's inventory will be reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. At June 30, 2022, the balance of inventory is reduced by $0.2 million for excessive and obsolete inventory.

Revenue from Contracts with Customers

The Company recognizes revenue at a point in time when it satisfies performance obligations by transferring control of promised goods to its customers. The amount of revenue recognized is equal to the consideration which the Company is entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be collected from a customer. Sales contracts often involve the sale and delivery of multiple products, each of which typically represent a separate performance obligation in the contract. While the Company sells these products on a stand-alone basis at their respective stand-alone selling prices ("SSP"), initial customer contracts will primarily involve the bundling of products which will be delivered concurrently to the customer. In such instances, the full consideration of the contract will be recognized upon shipment of the products. The Company generally requires receipt of full payment prior to shipment, however, from time to time, payment terms may be extended to customers upon which the Company will perform a necessary credit evaluation to ensure future collectability of the outstanding balance. The Company does not believe any portion of the outstanding accounts receivable balance to be uncollectible, and has therefore not recorded an allowance against the accounts receivable balance. Refer to Note 10 for further details.

Product Warranty

The Company provides a standard warranty on eligible products which provides the customer assurances that the products comply with the agreed-upon specifications. The standard warranty does not provide any services in addition to those assurances. The Company accrues a warranty reserve for products sold based upon the best estimate of the nature, frequency, and costs of future claims. These estimates are inherently uncertain given the short history of sales, and changes to the historical or projected warranty experience may cause material changes to the warranty reserve in the future. The warranty reserve is included within Accrued expenses on the consolidated balance sheets. Warranty expense is recorded as a component of Cost of Revenues in the consolidated statements of operations and comprehensive loss.

Warranty accrual activity consisted of the following for the three-month and six-month periods ended June 30, 2022 and 2021 (in thousands):

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2022	2021	2022	2021
Beginning balance	$ 97	$ —	$ 80	$ —
Add: Accruals for warranties issued during the period	25	—	42	—
Less: Settlements made during the period	—	—	—	—
Ending balance	$ 122	$ —	$ 122	$ —

Net Loss per Share

The Company calculates basic net loss per share by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by giving effect to all potential dilutive common stock equivalents outstanding during the period. For purposes of this calculation, options to purchase common stock and common stock warrants are considered common stock equivalents. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted net loss per share.

Basic and diluted net loss per common share is the same for all periods presented because all warrants, stock options and restricted stock units outstanding are anti-dilutive.

The following outstanding stock options, warrants and restricted stock units were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	Six-Month Periods Ended June 30,	
	2022	2021
Common stock warrants	7,310,917	600
Common stock options	5,608,140	5,827,524
Restricted stock units	—	89,273
Total	12,919,057	5,917,397

Recent Accounting Pronouncements

There are no recent accounting pronouncements that impact the Company's operations.

3. Fair Value of Financial Instruments

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels, and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below.

Level 1 - Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include money market funds.

Level 2 - Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include commercial paper, corporate bonds, U.S. Treasury Securities, and asset-backed securities.

Level 3 - Unobservable inputs for which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. The Company did not classify any of its investments within Level 3 of the fair value hierarchy.

The following table sets forth the fair value of the Company's financial assets measured on a recurring basis as of June 30, 2022 and December 31, 2021, respectively (in thousands):

		June 30, 2022				December 31, 2021			
Assets	**Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market funds	Cash and cash equivalents	$ 13,502	$ —	$ —	$ 13,502	$ 23,675	$ —	$ —	$ 23,675
Total assets measured at fair value		$ 13,502	$ -	$ —	$ 13,502	$ 23,675	$ —	$ —	$ 23,675

The Company did not have any financial liabilities measured on a recurring basis as of June 30, 2022 or December 31, 2021.

During the six-month period ended June 30, 2022, there were no transfers between Level 1, Level 2 or Level 3 assets or liabilities reported at fair value on a recurring basis and the valuation techniques used did not change compared to the Company's established practice.

4. Balance Sheet Components

Inventory

Inventory consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 3,497	$ 2,010
Work in process	1,788	1,371
Finished goods	2,586	2,443
Total inventory	$ 7,871	$ 5,824

Property and Equipment, Net

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

	June 30, 2022	December 31, 2021
Leasehold improvements	$ 2,519	$ 2,519
Laboratory equipment	1,333	1,019
Furniture, fixtures, and equipment	932	932
Software	289	202
Construction in progress	56	186
	5,129	4,858
Less: Accumulated depreciation	(2,743)	(2,396)
Property and equipment, net	$ 2,386	$ 2,462

Depreciation expense was $0.2 million and $0.1 million for the three-month periods ended June 30, 2022 and 2021, and $0.3 million and $0.2 million for the six-month periods ended June 30, 2022 and 2021.

Intangible Assets, Net

Intangible assets primarily consist of acquired licenses to utilize certain patents, know-how and technology relating to the Company's NPS technology for biomedical applications acquired from Old Dominion University Research Foundation ("ODURF"), Eastern Virginia Medical School, and the University of Southern California. In addition, the Company entered into a Sponsored Research Agreement with Old Dominion University's Frank Reidy Research Center for Bioelectrics, which includes certain intellectual property rights arising from the research. The Company is amortizing the intangible assets over an estimated useful life of 12 years.

Intangible assets, net consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Acquired patents and licenses	$ 7,985	$ 7,985
Less: Accumulated amortization	(5,102)	(4,769)
Intangible assets, net	$ 2,883	$ 3,216

A schedule of the amortization of intangible assets for the remainder of 2022 and the succeeding four fiscal years is as follows (in thousands):

Year Ending December 31:	
2022 (remaining 6 months)	$ 332
2023	665
2024	665
2025	665
2026	556
Total	$ 2,883

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Compensation	$ 3,695	$ 2,932
Controlled launch (Note 9)	267	534
Clinical trial costs and fees	134	245
Professional fees	202	85
Warranty	122	80
Other	255	513
D&O insurance (Note 12)	82	—
Total accrued expenses	$ 4,757	$ 4,389

Accrued compensation at June 30, 2022, includes a discrete charge of $0.2 million related to a reduction in force initiated on March 31, 2022. See Note 13 for additional details.

5. Goodwill

In 2014, the Company acquired three companies (the "Acquisitions") for aggregate consideration of $5.5 million. In accordance with ASC Topic 805, *Business Combinations*, the Company recorded goodwill of $2.8 million in connection with the Acquisitions as the consideration paid exceeded the fair value of the net tangible assets and the intangible assets acquired.

The Company reviews goodwill for impairment at least annually or whenever changes in circumstances indicate that the carrying amount of goodwill may not be recoverable. Based on the Company's annual impairment test as of December 31, 2021 the Company determined that no impairment of goodwill existed and was not aware of any indicators of impairment at such date. In addition, there were no indicators of impairment at June 30, 2022.

6. Stockholders' Equity and Stock-Based Compensation

Rights Offering

On June 9, 2022, the Company completed a rights offering (the "2022 Rights Offering) resulting in the sale of 7,317,072 units (the "Units"), at a price of $2.05 per Unit, with each Unit consisting of one share of the Company's common stock, par value $0.001 per share, and one warrant (the "2022 Rights Offering Warrants") to purchase one share of common stock. The common stock and warrants comprising the Units separated upon the closing of the 2022 Rights Offering and were issued individually. 7,317,072 shares of common stock and warrants to acquire up to an additional 7,317,072 shares of common stock were issued in the 2022 Rights Offering. The Company received aggregate gross proceeds from the 2022 Rights Offering of $15 million. If exercised, additional gross proceeds of up to $15 million may be received through the exercise of the 2022 Rights Offering Warrants issued in the 2022 Rights Offering. Each 2022 Rights Offering Warrant is exercisable for one share of the Company's common stock at an exercise price equal to $2.05. The 2022 Rights Offering Warrants are exercisable immediately and expire on the fifth anniversary of the closing of the 2022 Rights Offering. The 2022 Rights Offering Warrants are subject to redemption by the Company for $0.01 per underlying share of common stock, on not less than 30 days written notice, if the volume weighted average price of the Company's common stock equals or exceeds 200% of the exercise price for the warrants, subject to adjustment, per share, for 20 consecutive trading days, provided that the Company may not redeem the warrants prior to the date that is three months after the issuance date.

Private Placement Securities Purchase Agreement

On June 30, 2021, the Company entered into a Securities Purchase Agreement with Robert W. Duggan, the Company's largest stockholder and Board Chairman, pursuant to which the Company issued and sold to Mr. Duggan 3,048,780 shares of the Company's common stock, par value $0.001 per share, in a private placement (the "Private Placement"), at a price per share of $16.40, which was the market closing price on the date of the transaction. These shares were paid for through (i) the conversion of $41.0 million aggregate principal amount, together with all accrued and unpaid interest outstanding, owed to Mr. Duggan under the Loan Agreement by and between the Company and Mr. Duggan (Note 8), and (ii) additional cash in the amount of approximately $8.4 million. Upon the closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement terminated, without any early termination fees or penalties being owed by the Company, and no additional amounts were owed to Mr. Duggan under the Loan Agreement. The cash proceeds of approximately $8.4 million were received by the Company in July 2021.

At-the-Market Equity Offering

On February 4, 2021, the Company entered into a sales agreement (the "Sales Agreement") with Stifel, Nicolaus & Company, Inc. ("Stifel") as sales agent, pursuant to which the Company may offer and sell, from time to time, through Stifel, up to $60.0 million in shares of common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company has no obligation to make any sales of its common stock pursuant to such Sales Agreement. During the six-month period ended June 30, 2022, the Company did not issue or sell any shares of common stock under the Sales Agreement. During the six-month period ended June 30, 2021, the Company issued and sold 288,490 shares of common stock under the Sales Agreement. The shares were sold at a weighted average price of $27.73 per share for aggregate net proceeds of approximately $7.4 million, after deducting sales commissions and offering costs payable by the Company.

Common Stock Warrants

In connection with a private placement in November 2014 of the Company's common stock, par value $0.001 per share, the Company issued warrants as compensation to the placement agent to purchase a total of 299,625 shares of its common stock at an exercise price of $2.67 per share (the "Private Placement Warrants"). The Private Placement Warrants were exercisable for a period of seven years from issuance. In March 2021, warrants to purchase 45,638 shares of common stock were net exercised, resulting in the issuance of 40,563 shares of common stock. In November 2021, the last remaining 600 Private Placement Warrants expired unexercised, resulting in no further Private Placement Warrants outstanding.

In connection with the closing of the Company's initial public offering in May 2016, the Company issued warrants as compensation to its underwriters, to purchase a total of 574,985 shares of its common stock at an exercise price of $5.00 per share (the "IPO Warrants"). The IPO Warrants were exercisable for a period of five years from issuance. In March 2021, warrants to purchase 85,385 shares of common stock were net exercised, resulting in the issuance of 68,958 shares of common stock. All IPO Warrants were exercised prior to their expiration in May 2021, resulting in no further IPO Warrants outstanding.

In connection with a June 2020 rights offering, the Company issued warrants (the "2020 Rights Offering Warrants") to purchase a total of 641,571 shares of its common stock at an exercise price of $7.01. These 2020 Rights Offering Warrants were exercisable immediately and expired on the fifth anniversary of the completion of the Rights Offering, or June 16, 2025, subject to certain redemption rights by the Company. The 2020 Rights Offering Warrants were subject to redemption by the Company, on or after December 16, 2020, six months after the issuance date, for $0.01 per warrant, with not less than 30 days written notice, if the volume weighted average price of our common stock equaled or exceeded 200% of the exercise price for the 2020 Rights Offering Warrants for 10 consecutive trading days. On December 31, 2020, the Company met the requirements for redemption of these warrants and delivered a notice of redemption to redeem all of the outstanding warrants that remained unexercised at February 5, 2021, for the redemption price of $0.01 per warrant. Pursuant to the redemption, the Company redeemed 5,139 warrants. Prior to the February 5, 2021 redemption date, 636,432 warrants were exercised, generating approximately $4.5 million of total gross proceeds to the Company. As of June 30, 2022, there were no 2020 Rights Offering Warrants outstanding.

In connection with the 2022 Rights Offering, the Company issued 2022 Rights Offering Warrants to purchase a total of 7,317,072 shares of its common stock at an exercise price of $2.05. The 2022 Rights Offering Warrants are exercisable immediately and expire on the fifth anniversary of the closing of the 2022 Rights Offering. The 2022 Rights Offering Warrants are subject to redemption by the Company for $0.01 per underlying share of common stock, on not less than 30 days written notice, if the volume weighted average price of the Company's common stock equals or exceeds 200% of the exercise price for the warrants, subject to adjustment, per share, for 20 consecutive trading days, provided that the Company may not redeem the warrants prior to the date that is three months after the issuance date. A total of 6,155 warrants were exercised in June 2022. As of June 30, 2022, there were 7,310,917 2022 Rights Offering Warrants outstanding.

Equity Plans

2017 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan

The Board of Directors of the Company (the "Board") previously adopted, and the Company's stockholders approved, the Company's 2017 Equity Incentive Plan (the "2017 Plan").

The 2017 Plan has a 10-year term, and provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, and performance shares to employees, directors and consultants of the Company and any parent or subsidiary of the Company, as the Compensation Committee of the Board may determine. Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards under the 2017 Plan. In addition, shares remaining available under the Company's 2015 Equity Incentive Plan, as amended (the "2015 Plan"), and shares reserved but not issued pursuant to outstanding equity awards that expire or terminate without being exercised or that are forfeited or repurchased by the Company will be added to the shares of common stock available for issuance under the 2017 Plan. The 2017 Plan is administered by the Board's Compensation Committee. Effective January 1, 2022, the number of shares of common stock available under the 2017 Plan increased automatically by 1,188,657 shares pursuant to the evergreen provision of the 2017 Plan, which provides that the number of shares available to grant under the 2017 Plan will increase each year by the lesser of (i) 1,200,000 shares, (ii) 4% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. As of June 30, 2022, 2,271,900 shares of common stock remained available for issuance under the 2017 Plan.

In November 2017, the Board adopted the 2017 Inducement Equity Incentive Plan (the "Inducement Plan") and reserved 1,000,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the Inducement Plan. The Inducement Plan was adopted without stockholder approval.

The Inducement Plan has a 10-year term, and provides for the grant of equity-based awards, including nonstatutory stock options, restricted stock units, restricted stock, stock appreciation rights, performance shares and performance units, and its terms are substantially similar to the 2017 Plan, including with respect to treatment of equity awards in the event of a "merger" or "change in control" as defined under the Inducement Plan. Options issued under the Inducement Plan may have a term up to ten years and have variable vesting provisions. New hire grants generally vest 25% per year starting upon the first anniversary of the grant. Equity-based awards issued under the Inducement Plan are only issuable to individuals not previously engaged as employees or as non-employee directors of the Company prior to the Inducement Plan's adoption date. In May 2021, the Board approved an amendment to the Inducement Plan to reserve an additional 1,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan. As of June 30, 2022, 793,139 shares of common stock remained available for issuance under the Inducement Plan.

A summary of stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the six-months ended June 30, 2022 is presented below:

	Stock Options Outstanding	
	Number of shares	Weighted average exercise price
Balances — December 31, 2021	5,996,813	$ 15.77
Options granted	986,600	
Options exercised	-	
Options canceled	(1,023,018)	
Options expired	(352,255)	
Balances — June 30, 2022	5,608,140	$ 14.05
Exercisable — June 30, 2022	3,473,416	$ 16.09

Time-based Options

The Company awards time-based options which vest and become exercisable, subject to the individual's continued employment or service through the applicable vesting date. Time-based options can have various vesting schedules, most commonly new hire grants which generally vest 25% per year starting upon the first anniversary of the grant.

A summary of the time-based stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the six-months ended June 30, 2022 is presented below:

	Stock Options Outstanding		
	Number of shares		Weighted average exercise price
Balances — December 31, 2021	4,796,716	$	16.44
Options granted	786,600		
Options exercised	-		
Options canceled	(277,018)		
Options expired	(285,380)		
Balances — June 30, 2022	5,020,918	$	14.47
Exercisable — June 30, 2022	3,217,744	$	16.43

Performance Options

Certain stock options awarded to the Company's executives and other key employees contain performance conditions related to certain financial measures and achievements of strategic/operational milestones. The options will vest and become exercisable once the specific performance condition is fulfilled.

A summary of the performance option activity under the 2017 Plan and Inducement Plan for the six-months ended June 30, 2022 is presented below:

	Stock Options Outstanding		
	Number of shares		Weighted average exercise price
Balances — December 31, 2021	1,200,097	$	13.11
Options granted	200,000		
Options exercised	-		
Options canceled	(746,000)		
Options expired	(66,875)		
Balances — June 30, 2022	587,222	$	10.44
Exercisable — June 30, 2022	255,672	$	11.88

The Company estimates the fair value of employee stock options on the grant date using the Black-Scholes option pricing model. The estimated fair value of employee stock options is amortized on a straight-line basis over the requisite service period of the awards. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. Due to the limited trading history of the Company's common stock, the Company utilizes a portfolio of comparable companies to estimate volatility. The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2022	2021	2022	2021
Expected term in years	5.3 - 6.3	5.3 - 6.1	5.3 - 6.8	5.3 - 6.1
Expected volatility	88%	78%	83 - 88%	78%
Risk-free interest rate	3.0%	0.9 - 1.0%	1.9 - 3.0%	0.9 - 1.1%
Dividend yield	—	—	—	—

2017 Employee Stock Purchase Plan

The Board previously adopted and the stockholders approved the Company's 2017 Employee Stock Purchase Plan (the "2017 ESPP").

The 2017 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of Company common shares at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 250,000 common shares of the Company were available for purchase at adoption of the 2017 ESPP. Pursuant to the 2017 ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 450,000 shares, (ii) 1.5% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. The Board waived the evergreen provision for 2022 and no additional shares were reserved under the 2017 ESPP. During the three- and six-month periods ended June 30, 2022, the Company issued 85,844 shares of common stock under the 2017 ESPP. As of June 30, 2022, 563,252 shares of common stock remained available for issuance under the 2017 ESPP.

The Company estimated the fair value of ESPP on the grant date using the Black-Scholes option pricing model. The estimated fair value of ESPP is amortized on a straight-line basis over the requisite service period of the awards. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The Company utilizes its estimated volatility in the Black-Scholes option pricing model to determine the fair value of ESPP. The fair value of ESPP was estimated using the following weighted-average assumptions:

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2022	2021	2022	2021
Expected term in years	0.5 - 1.0	0.5 - 1.0	0.5 - 1.0	0.5 - 1.0
Expected volatility	83%	78%	83%	78%
Risk-free interest rate	0.6 - 0.9%	0.07 - 0.08%	0.6 - 0.9%	0.07 - 0.1%
Dividend yield	—	—	—	—

Stock-based Compensation

Total stock-based compensation expense consisted of the following (in thousands):

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2022	2021	2022	2021
Cost of revenues	$ 90	$ —	$ 180	$ —
Research and development	496	1,002	953	4,168
Sales and marketing	362	500	816	2,261
General and administrative	765	946	1,771	2,984
Total stock-based compensation expense	$ 1,713	$ 2,448	$ 3,720	$ 9,413

As of June 30, 2022, not all of the performance conditions of the performance options are probable to be achieved. Compensation expense has only been recognized for those conditions that are assumed to be probable.

In February 2021, the Compensation Committee approved of a modification to certain vesting conditions of outstanding Performance Options. The Company had not recognized any compensation expense in relation to these Performance Options as the performance condition was previously deemed to be improbable. However, upon modification those specific performance conditions are now deemed probable and fully vested. As such, during the three-month period ended March 31, 2021, the full expense in relation to the amended performance conditions was recognized resulting in $4.2 million of additional stock-compensation expense.

Total stock-based compensation expense by type was as follows (in thousands):

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2022	2021	2022	2021
Time-based options	$ 1,445	$ 1,917	$ 3,252	$ 3,686
Performance options	132	387	215	5,528
ESPP	136	144	253	199
Total stock-based compensation expense	$ 1,713	$ 2,448	$ 3,720	$ 9,413

7. Research Grants and Agreements

Sponsored Research Agreement

The Company may sponsor research activities ("SRAs") performed by ODURF. ODURF is compensated by the Company for its conduct of each study in accordance with the budget and payment terms set forth in the applicable task order. In March 2021, the Company agreed to sponsor a task order in the amount of $0.3 million for research performed during the subsequent 12-month period to be funded through monthly payments to ODURF. In May 2021, the Company agreed to sponsor an additional task order in the amount of $0.3 million for research performed during the subsequent 12-month period. These SRAs are funded through monthly payments to ODURF. Payments will be made upon ODURF certifying, to the Company's reasonable satisfaction, that ODURF has met its obligations pursuant to the specified task order and statement of work. The principal investigator may transfer funds with the budget as needed without the Company's approval so long as the obligations of ODURF under the task order and statement of work remain unchanged and unimpaired. During each of the three-month periods ended June 30, 2022 and 2021, the Company incurred costs relating to the SRAs equal to $0.1 million, and during the six-month periods ended June 30, 2022 and 2021, the Company recorded costs relating to the SRAs equal to $0.2 million and $0.1 million, respectively. As of June 30, 2022, there no unbilled SRAs left under the task orders.

8. Commitments and Contingencies

Loan Agreement

On March 11, 2021, the Company and Robert W. Duggan, the Board Chairman, entered into a Loan Agreement in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company. The Loan Agreement bore interest at a rate per annum equal to 5.0%, payable quarterly commencing on July 1, 2021. During the six-month period ended June 30, 2021, the Company recorded $0.6 million of interest expense in relation to this Loan Agreement. During the six-month period ended June 30, 2022, there was no interest expense recorded in relation to this Loan Agreement. In June 2021, the Loan Agreement was terminated and $41.0 million principal, together with approximately $0.6 million of accrued and unpaid interest, was fully settled via issuance of the Company's common stock at a price per share of $16.40. Refer to Note 6 for additional details of the private placement sale.

Insurance Loan Agreement

On May 13, 2021, the Company secured its annual director and officer liability insurance policy. The total premiums for the policy were approximately $2.6 million, of which the Company made a down payment of $0.7 million and financed the balance of $1.9 million via an Insurance Loan Agreement. The Insurance Loan Agreement had an annual interest rate of 3.69% and required monthly payments through February 2022, upon which the Insurance Loan Agreement was paid in full. At June 30, 2022, there was no outstanding portion of this Insurance Loan Agreement recorded on the balance sheet.

Operating Leases

In January 2017, the Company entered into a five-year lease (the "Existing Lease") for approximately 15,700 square feet for its corporate headquarters located in Hayward, California. The lease commenced in July 2017.

In May 2019, the Company entered into Lease Amendment 1 (the "Lease Amendment") in relation to the Existing Lease and added the lease of new premises of approximately 13,300 square feet and 21,300 square feet, ("Expansion Premises 1" and "Expansion Premises 2", respectively). Additionally, the term of the Existing Lease was extended to October 2029 to be coterminous with Expansion Premises 1 and Expansion Premises 2.

The Company evaluated the lease amendment under the provisions of ASC 842. It concluded that the Lease Amendment would be accounted for as a single contract with the Existing Lease because the additional lease payments due to the Lease Amendment was not commensurate with the right-of-use asset granted to the Company. Though the Lease Amendment was accounted for as a single contract, the Existing Premises, Expansion Premises 1 (occupied in November 2019) and Expansion Premises 2 (occupied in May 2020) are accounted for as separate lease components. Accordingly, the Company measured and allocated consideration to each lease component as of the modification date.

Information related to the Company's right-of-use assets and related lease liabilities are as follows (in thousands, except for remaining lease term and discount rate):

Year Ending December 31:		
2022 (remaining 6 months)	$	911
2023		1,845
2024		1,910
2025		1,977
2026		2,046
Thereafter		6,191
Total lease payments		14,880
Less imputed interest		(4,435)
Total lease liabilities	$	10,445
Other supplemental information:		
Current operating lease liabilities	$	827
Non-current operating lease liabilities		9,618
Total lease liabilities	$	10,445
Cash paid for operating lease liabilities	$	894
Weighted average remaining lease term		7.34
Weighted average discount rate		10%

Rent expense, including common area maintenance charges, was $0.5 million for each of the three-month periods ended June 30, 2022 and 2021; and was approximately $1.0 million during the six-month periods ended June 30, 2022 and 2021, respectively.

Legal Proceedings

The Company maintains indemnification agreements with its directors and officers that may require the Company to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law.

From time to time, the Company may be involved in a variety of claims, lawsuits, investigations, and proceedings relating to securities laws, corporate governance, product liability and promotion, patent infringement, contract disputes, employment disputes, and other matters relating to various claims that arise in the normal course of the Company's business, such as demands to inspect Company records and correspondence from the SEC and other government officials. The Company currently believes that these ordinary course matters are not material to the consolidated financial statements of the business; however, the results of litigation and claims are inherently unpredictable.

In February 2022, a civil securities lawsuit was filed in the U.S. District Court for the Northern District of California against the Company and certain of its executive officers, following the Company's announcement on February 8, 2022 that it had received an AI letter from the FDA indicating that the FDA did not believe the Company provided sufficient clinical evidence to support its 510(k) submission to add the treatment of sebaceous hyperplasia to the CellFX System's current U.S. labeling, and the subsequent decline of the market price of the Company's common stock. The lawsuit seeks class certification, unspecified damages, fees, costs, and expenses. Based upon currently available information, the Company believes the allegations in this case are without merit and will defend itself vigorously against them; however, litigation is inherently uncertain. The Company expects to file a motion to dismiss the case later this year, and an estimate of possible loss or range of loss, if any, cannot be made at this time.

9. Controlled Launch

In February 2021, the Company received 510(k) clearance from the FDA for its proprietary CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin. In January 2021, the Company received CE marking approval for the CellFX System, which allows for marketing of the system in the EU for treatment of general dermatologic conditions, including SH, SK, and cutaneous non-genital warts. Additionally, in June 2021 the Company received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada for use in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions. In February 2021, the Company commenced a controlled launch of the CellFX System in the United States and European Union via its CellFX Expectations Excelled Program (the "Controlled Launch"). Subsequent to receiving Health Canada approval in June 2021, the Company also commenced its Controlled Launch in Canada.

As part of the Controlled Launch, the Company selected 70 physicians and their practices to be the first physician consultants to launch the CellFX System and the associated CellFX commercial procedures into their respective markets and geographies. According to the Controlled Launch program, the Company provides and sets up a CellFX System at each physician site and provides the physician with the necessary related products and components, free of charge, to complete the requirements of the Controlled Launch. Each CellFX System and any unused component products remain the property of the Company throughout the Controlled Launch. Each physician identifies and recruits up to 40 or 50 patients, depending on the contract, for participation in the Controlled Launch, performing a CellFX procedure on each of the appropriately selected patients. Under the Controlled Launch, the physician and their patients complete evaluation surveys about their experiences with the CellFX System and provide other information helpful to the Company. Upon completion of the procedures and the survey feedback, the physician earns either credits which can be used towards the future purchase of the CellFX System or, in some jurisdictions, fair payment for their time and effort completing the paperwork required under the Controlled Launch program. Credits earned and, if applicable, any other payments earned are limited to a maximum amount dependent on the number of surveys received by the Company. Upon completion of the Controlled Launch, each physician may choose to either enter into a purchase agreement with the Company, under which the physician may use the credits earned (or other payments earned, as applicable) towards the purchase of the already-delivered CellFX System, or the physician must return the CellFX System to the Company.

As patient procedures and surveys are completed under the Controlled Launch program, the Company accrues the value of the credits earned, which are recorded in accrued expenses, with a corresponding charge to sales and marketing expense. The Company recorded sales and marketing expense in relation to the Controlled Launch of $0.1 million and $0.4 million, for the three-month periods ended June 30, 2022 and 2021, respectively, and $0.6 million for each of the six-month periods ended June 30, 2022 and 2021.

During the three- and six-month periods ended June 30, 2022, certain consultants completed the Controlled Launch and entered into purchase agreements with the Company, whereby they used their credits or other earned payments towards the purchase of a CellFX System. Accordingly, approximately $0.1 million and $0.4 million of the accrued liability related to the Controlled Launch was relieved and recognized as revenue on a non-cash basis as a result of these purchases during the three- and six-month periods ended June 30, 2022, respectively. See Note 10 for additional detail of revenue transactions.

10. Revenue

The Company recognizes revenue at a point in time when it satisfies performance obligations by transferring control of promised goods to its customers. The amount of revenue recognized is equal to the consideration which the Company is entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be collected from a customer. This consideration may include non-cash services performed, as is the case with revenue recognized in connection with the Controlled Launch. Total revenue recognized for the three-month period ended June 30, 2022 was $0.3 million, of which approximately $0.1 million was driven by the redemption of non-cash credits earned as part of the Controlled Launch, with the balance of approximately $0.2 million driven by cash purchases of cycle units ("CUs") and two CellFX commercial consoles. Total revenue recognized for the six-month period ended June 30, 2022 was $0.7 million, of which approximately $0.4 million was driven by the redemption of non-cash credits earned as part of the Controlled Launch, with the balance of approximately $0.3 million driven by cash purchases of CUs and three CellFX commercial consoles.

Sales contracts often involve the sale and delivery of multiple performance obligations in the contract.

Performance Obligations

Systems consist of the CellFX console and its embedded software, handpieces, and disposable tips. The console is a physical piece of hardware used by the customer to perform patient procedures. Individually the console and software are not distinct, therefore the Company combines the console and embedded software to form one distinct system performance obligation. Payment for systems is generally due prior to shipment, and the system performance obligation is satisfied upon shipment of the system to the customer.

Handpieces are attached to the console and used in conjunction with tips to perform patient procedures. Generally, upon initial sale of a system to a customer, the Company will include two handpieces. The handpiece has a shorter expected useful life than the console, and a customer can purchase additional handpieces when needed, as they are available for sale on a stand-alone basis. Payment for handpieces is generally due prior to shipment, and handpieces represent a distinct performance obligation which is satisfied either upon shipment, or upon delivery of the handpiece to the customer, depending on the specific contract.

Tips are single-patient multiple-use products that come in different sizes, each of which are to be used for specific procedures. Tips are attached to the handpiece for use in patient procedures and, upon detachment from the handpiece, a tip cannot be reused, and it must be disposed of. Tips represent a distinct performance obligation which is satisfied either upon shipment, or upon delivery of the tips to the customer, depending on the specific contract.

CUs are credits that authorize the customer to perform a procedure, or cycle. Each procedure requires a specific number of CUs, dependent upon type of tip used and procedure level selected. As the procedure is performed, the applicable number of CUs are decremented. When the customer's balance of CUs on a specific system is depleted, the system will no longer function until the customer purchases additional CUs. Customers can purchase additional CUs via the Company's CellFX Marketplace which is an online marketplace accessible directly from the CellFX System. Payment for CUs is due upon order placement and the CUs are immediately available for download to the console via CellFX CloudConnect. CUs represent a distinct performance obligation which is satisfied when CUs are made available for customers to download from the Company's CellFX CloudConnect, as customers can use purchased CUs at any time at their discretion, and the Company does not provide any ongoing service or other forms of involvement after the sale occurs.

Shipping and handling activities are not considered to be a separate performance obligation. The Company's standard commercial agreements generally include FOB shipping point terms. The Company has made an accounting policy election to account for shipping and handling costs as fulfillment costs because the shipping and handling activities occur after the customer obtains control of the product.

Transaction Price

The transaction price is the consideration to which the Company expects to be entitled to in exchange for providing the promised goods to customers. Customer orders placed for cash contemplate a fixed amount of consideration. Customer orders placed by physicians participating in the Controlled Launch when they elect to purchase the CellFX System are paid for via conversion of accumulated earned credits for prior services provided by the physicians under the terms of their participation in the Controlled Launch. For these transactions, the transaction price includes noncash consideration. The services rendered by the physicians are accounted for separately from the subsequent sales of the CellFX Systems because they are distinct from the system sales. They are distinct because they provide the Company with treatment data that can also be procured, and historically has been procured by the Company, without the corresponding system sales. This data is used by the Company to enhance marketing and promotion of its products.

The Company evaluates the possible impact of variable consideration in determining the transaction price, in particular the possibility of future returns or credits. Sales agreements allow for a right of return only if the product does not conform to the agreed upon quality standards or if the product was shipped due to Company error. The Company anticipates such returns will be minimal and has made no adjustments to the transaction price for any estimated returns. The transaction price is determined at the time of the initial revenue recognition and updated each quarter for any changes in circumstances (e.g., changes in estimated return or credit rates).

The Company has made an accounting policy election to exclude from the measurement of the transaction price all taxes which are imposed on and concurrent with a specific revenue-producing transaction and collected by the entity from a customer

When there are multiple performance obligations present, the total transaction price shall be allocated to each of the performance obligations based upon the relative SSPs of those performance obligations. The Company establishes SSPs based on multiple factors including, prices charged by the Company for similar offerings, product-specific business objectives, and the estimated cost to provide the performance obligation. However, upon the sale of a new CellFX System, all performance obligations are delivered concurrently and therefore there is no impact to revenue recognition timing, and the Company has determined allocations are not necessary. Should the customer purchase additional CUs, handpieces, or tips at a later time, those purchases will be made under separate purchase agreements, with all promised goods generally transferred at the same time, therefore no price allocation is necessary in that scenario either.

Controlled Launch Agreements

In August 2021 the Company began to recognize revenue in relation to the conversion of Controlled Launch program participants into sales agreements (Note 9). These customers were already in possession of the system, handpiece, and tips. As such, upon execution of these purchase agreements, the Company recognized revenue on the agreements because control of all performance obligations were transferred at that time. These customers separately purchased CUs in order to operate the CellFX System and the revenue for these CUs was recognized when the CUs are made available for customers to download from the Company's CellFX CloudConnect.

11. Segment Reporting

The Company operates and manages the business as one reportable and operating segment. The Company's Chief Executive Officer and Chief Financial Officer act as the chief operating decision makers ("CODM") of the Company. The CODM reviews the results of the Company on a consolidated basis, however in making certain operating decisions and assessing performance, the CODM will additionally review the disaggregated revenue results by product and geography. Substantially all of the Company's long-lived assets are based in the United States.

Revenue by product consisted of the following (in thousands):

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2022	2021	2022	2021
Systems	$ 209	$ —	$ 576	$ —
Cycle units	56	—	133	—
Total consolidated revenue	$ 265	$ —	$ 709	$ —

Revenue by geography consisted of the following (in thousands):

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2022	2021	2022	2021
North America	$ 214	$ —	$ 526	$ —
Rest of World	51	—	183	—
Total consolidated revenue	$ 265	$ —	$ 709	$ —

12. Related Party Transactions

On March 11, 2021, the Company and Robert W. Duggan, majority stockholder and Board Chairman, entered into a Loan Agreement in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company (Note 8).

On June 30, 2021, the Company and Mr. Duggan entered into a Securities Purchase Agreement (Note 6), pursuant to which the Company issued and sold to Mr. Duggan 3,048,780 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $16.40, for an aggregate investment in the amount of $50.0 million. The shares were paid for through (i) the conversion of the $41 million aggregate principal amount under the Loan Agreement, together with all accrued and unpaid interest outstanding, owed to Mr. Duggan under the Loan Agreement by and between the Company and Mr. Duggan (Note 8), and (ii) additional cash in the amount of approximately $8.4 million. Upon the closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement terminated, without any early termination fees or penalties being owed by the Company, and no additional amounts were owed to Mr. Duggan under the Loan Agreement.

In May 2022, the Company determined not to renew its annual director and officer liability insurance policy due to disproportionately high premiums quoted by insurance companies. Instead, on May 31, 2022, the Company and Robert W. Duggan, the Board Chairman, entered into a letter agreement (the "Letter Agreement") pursuant to which Mr. Duggan has agreed with the Company to personally provide indemnity coverage for a one-year period, and he has agreed to deposit cash and/or marketable securities into a third-party escrow, as security for these obligations, if requested by the Company. The Company will pay a fee of $1.0 million to Mr. Duggan that shall be due on May 31, 2023, the last day of the one-year period, in consideration of the obligations set forth in the Letter Agreement. As of June 30, 2022, the amount owed to Mr. Duggan under the Letter Agreement was $0.1 million, recorded on the balance sheet under accrued expenses.

13. Restructuring Charges

On March 31, 2022, the Company initiated a plan to reduce its operating expenses, preserve financial resources, and focus its sales and marketing efforts on increasing utilization of CellFX Systems. The Company's Board of Directors approved changes to the Company's commercial leadership, restructuring of its commercial field organization and reductions in other personnel and expenses across the Company. The Company announced a reduction in force effective as of March 31, 2022. The affected employees were offered separation benefits, including severance payments along with temporary healthcare coverage assistance. The Company incurred a discrete restructuring related charge of $0.7 million which was fully recorded in March 2022 and the related expenses are included within total cost and expenses on the condensed consolidated statement of operations for the six-month period ended June 30, 2022. This charge represents the total expected amount to be incurred in connection with the activity. During the three-months ended June 30, 2022, the Company paid $0.5 million of this balance. The remaining balance of $0.2 million is recorded on the balance sheet under accrued expenses and expected to be paid throughout 2022.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes included in this Quarterly Report and those in our Annual Report on Form 10-K.

Special Note Regarding Forward-Looking Statements

This report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "might," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, results of clinical studies, expectations regarding regulatory clearance and the timing of FDA or non-US filings or approvals including meetings with FDA or non-US regulatory bodies, procedures and procedure adoption, future results of operations, future financial position, our ability to generate revenues, our financing plans and future capital requirements, anticipated costs of revenue, anticipated expenses, the effect of recent accounting pronouncements, our investments, anticipated cash flows, our ability to finance operations from cash flows and similar matters, the impact of the recent COVID-19 coronavirus pandemic and related public health measures on our business, and statements based on current expectations, estimates, forecasts, and projections about the economies and markets in which we intend to operate and our beliefs and assumptions regarding these economies and markets. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. You should read the "Risk Factors" section of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained herein. We do not assume any obligation to update any forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. This Quarterly Report and any documents incorporated by reference may contain market data that we obtain from industry sources. These sources do not guarantee the accuracy or completeness of the information. Although we believe that our industry sources are reliable, we do not independently verify the information. The market data may include projections that are based on a number of other projections. While we believe these assumptions to be reasonable and sound as of the date of this Quarterly Report, actual results may differ from the projections.

Special Note Regarding Key Metrics

We review a number of metrics, including weekly utilization rates, to evaluate our business, measure our performance, identify trends affecting our business, formulate business plans and make strategic decisions. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview" for a discussion of how we calculate and use weekly utilization rates.

Our calculation of these metrics is not based on any standardized industry methodology and is not necessarily calculated in the same manner or comparable to similarly titled measures presented by other companies. Similarly, our measures of utilization rates may differ from estimates published by third parties or from similarly-titled metrics in the medical device industry due to differences in methodology. While these numbers are based on what we believe to be reasonable estimates for the applicable period of measurement, there are inherent challenges in measuring usage and engagement by our commercial customers around the world.

Overview

We are a novel bioelectric medicine company committed to health innovation using an entirely new and proprietary energy modality. The CellFX System is the first commercial product to harness the distinctive advantages of our proprietary Nano-Pulse Stimulation technology. The CellFX System delivers nanosecond duration pulses of electrical energy, each less than a millionth of a second long, to non-thermally clear targeted cells while sparing adjacent non-cellular tissue, to treat a variety of medical conditions for which an optimal solution remains unfulfilled.

In January 2021, we received CE marking approval for the CellFX System, which allows us to market the system in the European Union and, in June 2021, we received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada. The CE mark and Health Canada approvals allow us to market the CellFX System for use in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts. In February 2021, we received 510(k) clearance from the FDA for the CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin.

In February 2021, we initiated controlled launch programs in the United States and the European Union and in June 2021 we initiated a controlled launch program in Canada (collectively, our "Controlled Launch"). Under the Controlled Launch program, the physicians and their patients complete evaluation surveys about their experiences with the CellFX System and provide other information helpful to defining best practices for the introduction of the CellFX System into the clinic practice. A total of seventy clinics agreed to participate and were onboarded under the Controlled Launch program across the United States, Europe, and Canada. In August 2021, we began to convert Controlled Launch program participants into sales agreements, triggering revenue recognition. During the six-month period ended June 30, 2022, fourteen Controlled Launch program participants opted to purchase their CellFX System and ten clinics opted out of the program. As of June 30, 2022, a total of forty-three Controlled Launch program participants have opted to purchase their CellFX System and sixteen clinics have opted out of the program. An objective of the Controlled Launch program is to turn participating clinics into high utilization commercial customers that will serve as important reference clinics for future commercial customers.

We initially expected clinics to complete the program requirements within three to five months. However, the average time for clinics that have completed the Controlled Launch program has been seven months. We continue to gain valuable information from the Controlled Launch process. While the real-world delivery of NPS technology through the CellFX System has proven to clear benign lesions in clinical studies, we have learned that the market development for benign lesions and the integration of this procedure into the practice workflow will require a higher touch model to generate the system utilization we are expecting. We now expect clinics to continue to move through the program throughout 2022, as they complete the program requirements.

In May 2022, we selected nine of our commercial clinics across the United States, the European Union and Canada to collaborate with on developing commercial best practices to demonstrate the clinical and economic value of a CellFX System completely integrated in a dermatology practice. Our goal for these clinics is to perform forty commercial sessions per month on a consistent basis. Once this initial group has achieved this level of utilization, we expect to have a blueprint for the necessary training, education, and marketing required and will be in a position to apply this blueprint to the rest of our commercial clinics and new clinic sales going forward. Until we achieve our utilization goals, we will have a reduced emphasis on CellFX System sales into new clinics. We will continue to develop and build our capital sales pipeline and believe that as we reach our utilization goals, we will be well positioned to begin focusing on capital sales.

On March 31, 2022, we initiated a plan to reduce our operating expenses, preserve financial resources, and focus our sales and marketing efforts on increasing utilization of CellFX Systems. As a result of this focus, we initiated operating expense reduction programs across the Company. Our Board of Directors approved changes to our commercial leadership, restructuring of our commercial field organization and reductions in other personnel and expenses. We announced a reduction in force effective as of March 31, 2022. The affected employees were offered separation benefits, including severance payments along with temporary healthcare coverage assistance. We incurred a discrete restructuring related charge of $0.7 million which was fully recorded in March 2022 and the related expenses are included within total cost and expenses on the condensed consolidated statement of operations for the six-month period ended June 30, 2022. See Note 4 for further details.

We completed the commercial sale of three CellFX Systems in the six-month period ended June 30, 2022. The majority of our revenue for the three- and six-month periods ended June 30, 2022, was recognized on a non-cash basis when Controlled Launch program participants applied their earned credits towards the purchase of a CellFX System. See Note 9 for additional details of the Controlled Launch program and Note 10 for additional details of the revenue transactions.

We are pursuing specific indications for the CellFX System in the United States similar to the regulatory clearances we have received in Europe and Canada, requiring additional 510(k) submissions, and likely based on comparative clinical data. In December 2021, we submitted a 510(k) to add the treatment of SH to the CellFX System's indications for use in the United States. In February 2022 we received an AI letter from the FDA in response to the 510(k) submitted. In the AI letter, the FDA stated it did not believe the Company provided sufficient clinical evidence at this time to support the expanded indication for use, and that the Company had not met the primary endpoints of the SH FDA-approved IDE study. The Company met with the FDA at the end of April 2022 to gain clarification regarding the AI letter and to discuss the appropriate next steps. Following the meeting and at the FDA's request, the Company provided additional analysis of the sebaceous hyperplasia comparative clinical data. The Company met with the FDA again in June 2022 to discuss the data. Following this meeting, the FDA requested further data which was provided in July 2022. The Company is expecting feedback from the FDA on the most recent data provided. The Company expects to continue to collaborate with the FDA to formally respond to the AI letter. Separately, in August 2022, the Company received 510(k) clearance from the FDA for expanded energy settings for use with the family of CellFX System treatment tips in dermatology. The expanded energy settings enables clinicians in the U.S. to provide more customized energy delivery specific to individual lesions.

We have incurred substantial operating losses and have used cash in our operating activities since inception. Based on our current operating plan, we believe we do not have sufficient cash and cash equivalents on hand to support current operations for the twelve months following the filing of this Quarterly Report. Therefore, to finance our ongoing operations, we will need to raise additional capital or enter into a revenue-generating collaboration, which cannot be assured. We plan to seek to raise capital from time to time through public or private equity offerings, debt financings, our at-the-market equity offering program, or to enter into collaborations with third parties, to fund our future operations.

Over the past few years, Mr. Duggan has made significant investments in our Company to fund its operations. Mr. Duggan may or may not elect to participate in any number of our future fundraisings, as described above, and he may choose to invest more than his current pro rata share in any of these fundraisings, or alternatively he may offer to provide debt financing as may be needed in order to maintain the Company as a going concern.

The source, timing and availability of any future financing will depend largely upon market conditions and perceived progress in the CellFX commercial program, as well as future clinical and regulatory developments concerning the CellFX System and our other NPS-based technologies. Funding may not be available when needed, at all or on terms acceptable to us. Lack of necessary funds may require us to, among other things, delay, scale back or eliminate some or all of our commercial activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business. In addition, the recent decline in economic activity caused by the armed conflict between Russia and Ukraine and by the COVID pandemic, together with the deterioration of the credit and capital markets, could have an adverse impact on potential sources of future financing.

Plan of Operation

We plan to establish ourselves as a medical therapy company with a local, nonthermal, and drug-free treatment platform that initiates cell death in targeted tissue by a process of cell signaling. In order to accomplish this, we plan to:

Improve our technology by continuing our research and product development efforts. We expect to develop interchangeable tissue applicators to target different tissue types that will leverage the novel characteristics of our NPS technology platform.

Further explore and understand the benefits of our NPS technology platform with the objectives of broadening the currently planned cosmetic and therapeutic applications, while also identifying new applications. We anticipate that results of our clinical studies will enable us to recognize certain unmet medical needs that may be addressed by our technology.

Continue to protect and expand our intellectual property portfolio with respect to NPS technology, which we expect will increase our ability to deter competitors and position our Company for favorable licensing and partnering opportunities.

Partner with medical or biomedical device companies for certain applications which we anticipate may accelerate product development and acceptance into target market areas and allow us to gain the sales and marketing advantages of one or more established distribution infrastructures.

COVID-19 Pandemic

Our clinical trials may be affected by the COVID-19 pandemic. Site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 pandemic, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Also, it is possible that delivery from some of our suppliers of certain materials used in the production of our product candidates could be delayed due to COVID-19 which could affect our ability to obtain sufficient materials for our product candidates. COVID-19 has adversely affected global economies and financial markets and will likely continue to do so, resulting in an economic downturn that could affect demand for our product candidates and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. We cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. See the Risk Factors section for further discussion of the possible impact of the COVID-19 pandemic on our business.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with the rules and regulations of the SEC. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies and estimates are described in our Annual Report on Form 10-K for the year ended December 31, 2021. We continually evaluate the accounting policies and estimates used in preparing our consolidated financial statements. There have been no material changes to the Company's significant accounting policies during the six-month period ended June 30, 2022, as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Valuation of Inventory

Inventory is stated at lower of cost or net realizable value. We established the inventory basis by determining the cost based on standard costs approximating the purchase costs on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of our business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of our inventory will be reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. At June 30, 2022, the balance of inventory is reduced by $0.2 million for excessive and obsolete inventory.

Revenue from Contracts with Customers

We recognize revenue at a point in time as we satisfy performance obligations by transferring control of promised goods to our customers. The amount of revenue recognized is equal to the consideration which we are entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be collected from a customer. Sales contracts often involve the sale and delivery of multiple products, each of which typically represent a separate performance obligation in the contract. While we sell these products on a stand-alone basis at a particular stand-alone selling price ("SSP"), initial customer contracts will likely involve the bundling of products which will be delivered concurrently to the customer and have the same pattern of transfer. In such instances, the full consideration of the contract will be recognized upon delivery of the products. We include a standard warranty on our products which provides assurances that the products comply with agreed-upon specifications.

Recent Accounting Pronouncements

Refer to "Recent Accounting Pronouncements" in Note 2 of Notes to Condensed Consolidated Financial Statements of this Quarterly Report.

Segment and Geographical Information

We operate and manage our business as one reportable and operating segment. Our CODM reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of our long-lived assets are based in the United States. Refer to Note 11 of Notes to Condensed Consolidated Financial Statements of this Quarterly Report for disaggregated revenue results.

Results of Operations

Comparison of the three-month periods ended June 30, 2022 and 2021

Our condensed consolidated statements of operations as discussed herein are presented below:

	Three-Month Periods Ended June 30,		
(in thousands)	2022	2021	$ Change
Revenues:			
Product revenues	$ 265	$ —	$ 265
Total revenues	265	—	265
Cost and expenses:			
Cost of revenues	1,344	—	1,344
Research and development	5,458	7,459	(2,001)
Sales and marketing	3,690	3,147	543
General and administrative	3,787	4,200	(413)
Total cost and expenses	14,279	14,806	(527)
Loss from operations	(14,014)	(14,806)	792
Other income (expense):			
Interest income (expense), net	18	(517)	535
Total other income (expense)	18	(517)	535
Net loss	$ (13,996)	$ (15,323)	$ 1,327

Revenues

Revenues increased by $0.3 million to $0.3 million for the three-month period ended June 30, 2022, from zero during the same period in 2021 because we commenced sales agreement activity in August 2021 which triggered the recognition of revenue.

Cost of Revenues

Cost of revenues increased by $1.3 million to $1.3 million for the three-month period ended June 30, 2022, from zero during the same period in 2021. Prior to commercialization in August 2021, all uncapitalized manufacturing related overhead costs were recorded as research and development expenses. Upon commercialization, these costs are recorded as cost of revenue. Cost of revenue for the three-month period ended June 30, 2022 consisted primarily of the uncapitalized manufacturing related overhead costs for products assembled during the quarter. Substantially all of the inventory sold during the three-month period ended June 30, 2022, was previously reserved.

Research and Development

Research and development expenses consist of compensation and other related employee expenses for research and development personnel, clinical trials and consulting costs related to the design, development and enhancement of our potential future products, prototype material and devices. Prior to August 2021, research and development expense included uncapitalized manufacturing related overhead costs. Upon commercialization in August 2021, the Company began recording uncapitalized manufacturing related overhead costs as cost of revenues. Research and development expenses decreased by $2.0 million to $5.5 million for the three-month period ended June 30, 2022, from $7.5 million during the same period in 2021

primarily due to decreases of $0.7 million in compensation and other employee related expenses, $0.7 million in paid services and external research, $0.5 million in stock-based compensation, and $0.4 million in supplies; partially offset by $0.4 million of reduced manufacturing absorption. During the three-month period ended June 30, 2021, the Company was recording uncapitalized manufacturing related overhead costs in research and development, whereas during the three-month period ended June 30, 2022, the balance recorded in research and development was zero.

Sales and Marketing

Sales and marketing expenses consist of compensation and other related employee expenses for sales and marketing personnel, expenses associated with advertising and training, and marketing studies including our Controlled Launch program. Sales and marketing expenses increased by $0.5 million to $3.7 million for the three-month period ended June 30, 2022, from $3.1 million during the same period in 2021 primarily due to $0.7 million of increased compensation and other employee related expenses related primarily due to increased headcount. This is offset by decreases of $0.1 million in stock-based compensation and $0.1 million in paid services and promotional activities, primarily related to non-cash Controlled Launch expenses.

General and Administrative

General and administrative expenses consist of compensation and other related employee expenses for executives, finance, legal, human resources, information technology, and administrative personnel, professional fees, patent fees and costs, insurance costs and other general corporate expenses. General and administrative expenses decreased by $0.4 million to $3.8 million for the three-month period ended June 30, 2022, from $4.2 million during the same period in 2021 primarily due to decreases of $0.2 million in stock-based compensation, $0.1 million in insurance related costs, and $0.1 million of supplies.

Other Income (Expense)

Interest expense decreased by $0.5 million to zero for the three-month period ended June 30, 2022, from $0.5 million during the same period in 2021 primarily due to the interest associated with the Loan Agreement which was terminated in June 2021. Interest income was flat when comparing the three-month period ended June 30, 2022 to the same period in 2021.

Comparison of the six-month periods ended June 30, 2022 and 2021

Our condensed consolidated statements of operations as discussed herein are presented below:

	Six-Month Periods Ended June 30,		
(in thousands)	2022	2021	$ Change
Revenues:			
Product revenues	$ 709	$ —	$ 709
Total revenues	709	—	709
Cost and expenses:			
Cost of revenues	2,253	—	2,253
Research and development	12,227	16,522	(4,295)
Sales and marketing	9,231	7,293	1,938
General and administrative	8,285	9,516	(1,231)
Total cost and expenses	31,996	33,331	(1,335)
Loss from operations	(31,287)	(33,331)	2,044
Other income (expense):			
Interest income (expense), net	18	(631)	649
Total other income (expense)	18	(631)	649
Net loss	$ (31,269)	$ (33,962)	$ 2,693

Revenues

Revenues increased by $0.7 million to $0.7 million for the six-month period ended June 30, 2022, from zero during the same period in 2021 because we commenced sales agreement activity in August 2021 which triggered the recognition of revenue.

Cost of Revenues

Cost of revenues increased by $2.3 million to $2.3 million for the six-month period ended June 30, 2022, from zero during the same period in 2021. Prior to commercialization in August 2021, all uncapitalized manufacturing related overhead costs were recorded as research and development expenses. Upon commercialization, these costs are recorded as cost of revenue. Cost of revenue for the six-month period ended June 30, 2022 consisted primarily of the uncapitalized manufacturing related overhead costs for products assembled during the quarter. Substantially all of the inventory sold during the six-month period ended June 30, 2022, was previously reserved.

Research and Development

Research and development expenses consist of compensation and other related employee expenses for research and development personnel, clinical trials and consulting costs related to the design, development and enhancement of our potential future products, prototype material and devices. Prior to August 2021, research and development expense included uncapitalized manufacturing related overhead costs. Upon commercialization in August 2021, the Company began recording uncapitalized manufacturing related overhead costs as cost of revenues. Research and development expenses decreased by $4.3 million to $12.2 million for the six-month period ended June 30, 2022, from $16.5 million during the same period in 2021 primarily due to decreases of $3.2 million in stock-based compensation, $0.9 million of paid services and external research driven by clinical trial fees, $0.4 million of compensation and other employee related expenses and $0.4 million of supplies. These decreases are partially offset by $0.7 million of reduced manufacturing absorption. During the six-month period ended June 30, 2021, the Company was recording uncapitalized manufacturing related overhead costs in research and development, whereas during the six-month period ended June 30, 2022, the balance recorded in research and development was zero.

Sales and Marketing

Sales and marketing expenses consist of compensation and other related employee expenses for sales and marketing personnel, expenses associated with advertising and training, and marketing studies including our Controlled Launch program. Sales and marketing expenses increased by $1.9 million to $9.2 million for the six-month period ended June 30, 2022, from $7.3 million during the same period in 2021 primarily due to $2.3 million of increased compensation and other employee related expenses related primarily due to increased headcount, discrete restructuring related charge of $0.5 million, and $0.6 million of increased promotional activities. The increases were offset by decreases of $1.4 million in stock-based compensation and $0.2 million of non-cash Controlled Launch expenses. The increases in sales and marketing activities are attributable to our FDA clearance, CE marking approval, and Health Canada clearance as we commercialize our CellFX System.

General and Administrative

General and administrative expenses consist of compensation and other related employee expenses for executives, finance, legal, human resources, information technology, and administrative personnel, professional fees, patent fees and costs, insurance costs and other general corporate expenses. General and administrative expenses decreased by $1.2 million to $8.3 million for the six-month period ended June 30, 2022, from $9.5 million during the same period in 2021 primarily due to $1.2 million of decreased stock-based compensation.

Other Income (Expense)

Interest expense decreased by $0.6 million to zero for the six-month period ended June 30, 2022, from $0.6 million during the same period in 2021 primarily due to the interest associated with the Loan Agreement which was terminated in June 2021. Interest income was flat when comparing the six-month period ended June 30, 2022 to the same period in 2021.

Liquidity and Capital Resources

To date, we have not generated significant revenues from product sales. Since inception, we have funded our business primarily through the issuance of equity securities and debt. Over the next few years, we intend to invest in research and development to develop new applications for existing products and additional commercially viable products and to assess the feasibility of potential future products. Additionally, we expect that our general and administrative expenses will increase as we continue to incur incremental costs associated with being a public company and our sales and marketing expenses will increase as we continue to commercialize the CellFX System.

On February 4, 2021, we entered into a Sales Agreement with Stifel as sales agent, pursuant to which we may offer and sell, from time to time, through Stifel, up to $60.0 million in shares of our common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. We have no obligation to make any sales of our common stock pursuant to such Sales Agreement. During the six-month period ended June 30, 2022, we did not issue or sell any shares of common stock under the Sales Agreement. During the six-month period ended June 30, 2021, we issued and sold 288,490 shares of common stock under the Sales Agreement. The shares were sold at a weighted average price of $27.73 per share for aggregate net proceeds of approximately $7.4 million, after deducting sales commissions and offering costs payable by us.

In March 2021 we entered into a Loan Agreement with Robert W. Duggan, our Board Chairman, in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company. The Loan Agreement had a maturity date of June 11, 2022. Under the Loan Agreement, Mr. Duggan provided us, subject to certain conditions, an unsecured term loan facility in an original aggregate principal amount of $41.0 million. The Loan Agreement bore interest at a rate per annum equal to 5.0%, payable quarterly commencing on July 1, 2021. The Loan Agreement contained certain covenants and Events of Default.

On June 30, 2021, we entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which we issued and sold to Mr. Duggan 3,048,780 shares of our common stock, par value $0.001 per share, in a private placement, at a price per share of $16.40. The shares were paid for through (i) the conversion of the $41 million aggregate principal amount, together with all accrued and unpaid interest outstanding, pursuant to the Loan Agreement by and between us and Mr. Duggan (Note 8), and (ii) additional cash in the amount of approximately $8.4 million. Upon closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement was terminated, without early termination fees or penalties being owed by us, and no additional amounts were owed to Mr. Duggan under the Loan Agreement. The cash proceeds of approximately $8.4 million were received by us in July 2021.

On June 9, 2022, we completed the 2022 Rights Offering resulting in the sale of 7,317,072 Units, at a price of $2.05 per Unit, with each Unit consisting of one share of the Company's common stock, par value $0.001 per share, and one warrant to purchase one share of common stock. 7,317,072 shares of common stock and warrants to acquire up to an additional 7,317,072 shares of common stock were issued in the 2022 Rights Offering. The Company received aggregate gross proceeds from the 2022 Rights Offering of $15 million. If exercised, additional gross proceeds of up to $15 million may be received through the exercise of warrants issued in the 2022 Rights Offering. Each warrant is exercisable for one share of the Company's common stock at an exercise price equal to $2.05. Warrants are exercisable immediately and expire on the fifth anniversary of the closing of the 2022 Rights Offering.

Our condensed consolidated statements of cash flows as discussed herein are presented below:

	Six-Month Periods Ended June 30,	
(in thousands)	2022	2021
Net cash used in operating activities	$ (28,416)	$ (28,053)
Net cash provided by (used in) investing activities	(298)	7,854
Net cash provided by financing activities	14,898	55,162
Net increase (decrease) in cash and cash equivalents	$ (13,816)	$ 34,963

To date, we have generated limited revenue and used cash in our operating activities. As a result, we have incurred significant operating losses in each year since our inception and we may continue to incur additional losses for the next several years. As of June 30, 2022, the Company had an accumulated deficit of $267.5 million, cash outflows from operations of $28.4 million for the six months then ended, cash and cash equivalents of $14.8 million and a net loss of $31.3 million. These factors, combined with the Company's forecast of cash required to fund operations for a period of at least twelve months from the date of issuance of the accompanying consolidated financial statements, raise substantial doubt under ASC 205-40, *Presentation of Financial Statements – Going Concern* about the Company's ability to continue as a going concern within one year after the issuance of these consolidated financial statements. We plan to raise additional capital in the future to fund our operations through public or private equity offerings, debt financings, or our at-the-market equity offering program, or by entering into revenue-generating collaborations. Mr. Duggan, our majority stockholder, may elect to participate in any number of our future financings, or alternatively he may offer to provide debt financing as may be needed in order to maintain the Company as a going concern. We can give no assurance, at this time, that additional financing or a collaboration will be available when needed on terms acceptable to us, however.

These expectations are based on our current operating and financing plans which are subject to change. Until we are able to generate sustainable product revenues at profitable levels, we expect to finance our future cash needs through public or private equity offerings, debt financings, our at-the-market equity offering program, and/or potential new collaborations. Such additional funds may not be available on terms acceptable to us or at all. If we raise funds by issuing equity or equity-linked securities, the ownership of some or all of our stockholders will be diluted, and the holders of new equity securities may have priority rights over our existing stockholders. If adequate funds are not available, we may be required to curtail operations significantly or obtain funds by entering into agreements on unattractive terms. Our inability to raise capital could have a material adverse effect on our business, financial condition, results of operations and cash flows. For example, lack of necessary funds may require us to, among other things, delay, scale back or eliminate some or all of our commercial activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business. In addition, the recent decline in economic activity caused by the armed conflict between Russia and Ukraine and by the COVID pandemic, together with the deterioration of the credit and capital markets, could have an adverse impact on potential sources of future financing.

Operating Activities

Our primary uses of cash in operating activities are for ongoing product development and commercialization activities relating to our product and product candidates.

During the six-month period ended June 30, 2022, we used cash in the amount of $28.4 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, as well as increases in inventory and accounts payable.

During the six-month period ended June 30, 2021, we used cash in the amount of $28.1 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, as well as increases in inventory and prepaid and other current assets.

Investing Activities

Our investing activities consist primarily of investment purchases, sales and maturities and capital expenditures.

During the six-month period ended June 30, 2022, $0.3 million of cash used in investing activities was driven by the purchase of property and equipment.

During the six-month period ended June 30, 2021, $7.9 million of cash provided by investing activities was primarily from $8.0 million of cash proceeds from the maturities of investments, partially offset by the purchase of property and equipment.

Financing Activities

During the six-month period ended June 30, 2022, cash provided by financing activities was $14.9 million, primarily due to $15.0 million of proceeds from the sale of common stock in our rights offering and $0.4 million from the sale of stock under our employee stock purchase plan, partially offset by payments made on the Insurance Loan Agreement.

During the six-month period ended June 30, 2021, cash provided from financing activities was $55.2 million, primarily due to $41.0 million net cash received from our Loan Agreement, $7.4 million net cash received from our at-the-market equity offering, $4.9 million received from stock option and warrant exercises, and $0.4 million received from the sale of stock under our employee stock purchase plan.

Contractual Obligations

There have been no material changes outside the ordinary course of our business to the contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

Off-Balance Sheet Arrangements

At June 30, 2022, we did not have any transactions, obligations or relationships that constitute off-balance sheet arrangements.

In the ordinary course of business, we enter into standard indemnification arrangements. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology, or from claims relating to our performance or non-performance under a contract. The maximum potential amount of future payments we could be required to make under these agreements is not determinable because it involves claims that may be made against us in future periods, but have not yet been made. To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

We also enter and have entered into indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law. In addition, we may have obligations to hold harmless and indemnify third parties involved with our fundraising efforts and their respective affiliates, directors, officers, employees, agents or other representatives against any and all losses, claims, damages and liabilities related to claims arising against such parties pursuant to the terms of agreements entered into between us and such third parties in connection with such fundraising efforts. No liability associated with such indemnification agreements has been recorded as of June 30, 2022.

Trends, Events and Uncertainties

Research and development of new technologies are, by their nature, unpredictable. Although we undertake development efforts with commercially reasonable diligence, there can be no assurance that the net proceeds from our financings will be sufficient to enable us to develop our technology to the extent needed to generate future sales to sustain our operations. If we do not continue to have enough funds to sustain our operations, we will consider other options to continue the commercialization of the CellFX System, including, but not limited to, additional financing through follow-on stock offerings, debt financings, or co-development agreements and /or other alternatives.

We cannot assure investors that our technology will be adopted or that we will ever achieve sustainable revenues sufficient to support our operations. Even if we are able to generate revenues, there can be no assurances that we will be able to achieve profitability or positive operating cash flows. There can be no assurances that we will be able to secure additional financing in the future on acceptable terms or at all. If cash resources are insufficient to satisfy our ongoing cash needs, we would be required to scale back or discontinue our technology and product development programs, or obtain funds, if available, although there can be no assurances, through the sale, licensing or strategic alliances that could require us to relinquish rights to our technology and intellectual property, or to curtail, suspend or discontinue our operations entirely.

See the section entitled “COVID-19 Pandemic” above and elsewhere in this Management’s Discussion and Analysis of Financial Condition and Results of Operations for a discussion of the current and potential future impact of COVID-19 on our business, financial condition and results of operation.

Other than as discussed above and elsewhere in this Quarterly Report, we are not currently aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition in the near term, although it is possible that new trends or events may develop in the future that could have a material effect on our financial condition.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes in market risk from the information provided in our Annual Report on Form 10-K for the year ended December 31, 2021. We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates. We do not hold financial instruments for trading purposes.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of June 30, 2022, our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act, as amended, that occurred during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Internal control over financial reporting means a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Inherent Limitations on Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. 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 controls. 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 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 may not be detected.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in a variety of claims, lawsuits, investigations, and proceedings relating to securities laws, product liability, patent infringement, contract disputes, and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications.

In February 2022, a civil securities lawsuit was filed in the U.S. District Court for the Northern District of California against the Company and certain of its executive officers, following the Company's announcement on February 8, 2022 that it had received an AI letter from the FDA indicating that the FDA did not believe the Company provided sufficient clinical evidence to support its 510(k) submission to add the treatment of sebaceous hyperplasia to the CellFX System's current U.S. labeling, and the subsequent decline of the market price of the Company's common stock. The lawsuit seeks class certification, unspecified damages, fees, costs, and expenses. Based upon currently available information, we believe the allegations in this case are without merit and we will defend vigorously against them. The Company expects to file a motion to dismiss the case later this year, and an estimate of possible loss or range of loss, if any, cannot be made at this time.

The results of legal proceedings and claims are inherently unpredictable. However, we do not believe any currently pending matters will have a material adverse effect on our business based on our current understanding of such matters.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report, including our financial statements and related notes, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially affect our business, financial condition, results of operations, and prospects. In addition, the impact of COVID-19 and any worsening of the economic environment may exacerbate the risks described below, any of which could have a material impact on us.

Summary

Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. These risks are described more fully below and include, but are not limited to, risks relating to the following:

Our limited operating history and our limited revenue producing operations;

Our inability to operate without additional fundraising;

Substantial doubt about our ability to continue as a going concern;

Competition within our industry;

Health epidemics, including the coronavirus pandemic;

Our reliance on certain third parties such as key suppliers;

Potential loss of key management personnel;

Potential security breaches, loss of data, and other disruptions to us or to our third-party service providers that could compromise sensitive information;

Potential product liability lawsuits and other litigation;

The timing, unpredictability, and expense of our clinical and product development activities;

The possibility of adverse trial results and unfavorable long-term trial data;

Potential failure to obtain and maintain necessary regulatory clearances or approvals;

Uncertainties concerning the long-term safety and effectiveness of our CellFX System and product candidates, and the potential for adverse side effects;
The commercial uncertainties concerning whether there will be broad adoption of our CellFX System and NPS technology;

Possible challenges enrolling patients in our clinical trials;

Uncertainties concerning our ability to obtain an adequate level of reimbursement by Medicare and other third-party payers;

Protection of intellectual property, potential litigation related to intellectual property, and obligations under intellectual property agreements;

Stringent domestic and foreign regulation in respect of any potential devices and products, including healthcare laws and regulations;

Healthcare policy changes;

Volatility of the price of our common stock;

Concentration of ownership by our principal stockholder and Board Chairman, Robert W. Duggan;

Unfavorable global economic or political conditions; and

Potential material weaknesses and uncertainties concerning our ability to maintain an effective system of internal control over financial reporting.

Risks Relating to Our Business, Industry and Financial Condition

Because we have a limited operating history and have recently commenced revenue producing operations, it is difficult to evaluate the future of our business.

We are a bioelectric medicine technology company and have recently commenced revenue producing operations. To date, our operations on a consolidated basis have consisted almost entirely of the continued development and clinical studies of our technologies and implementation of the early parts of our business plan. We have incurred significant operating losses in each year since our inception and we may continue to incur additional losses for the next several years. In addition, a high percentage of our expenses will continue to be fixed; accordingly, our losses may be greater than expected and our operating results may suffer. We have limited historical financial data upon which we may base our projected revenue and base our planned operating expenses. Our limited operating history makes it difficult to evaluate our technology, operations and business prospects.

We currently have very limited product revenue and we may never become profitable.

To date, we have not generated significant revenue and we have historically relied on financing from the sale of equity securities to fund our operations. We expect that our future financial results will depend primarily on our success in launching, selling, and supporting our therapies and procedures using the CellFX System or other products based on our NPS technology. We expect to expend significant resources on hiring of personnel, continued scientific and product research and development, potential product testing and preclinical and clinical investigation, intellectual property development and prosecution, marketing and promotion, capital expenditures, working capital, general and administrative expenses, and fees and expenses associated with our capital raising efforts. We expect to incur costs and expenses related to consulting costs, laboratory development costs, hiring of scientists, engineers, sales representatives, and other operational personnel, and the continued development of relationships with potential partners. We are incurring significant operating losses, we expect to continue to incur additional losses for at least the next several years, and we cannot assure you that we will generate substantial revenue or be profitable in the future. There are no assurances that our future products will be cleared or approved or become commercially viable or accepted for use. Even with commercially viable applications of our technology, which may include licensing, we may never recover our research and development expenses.

Investment in medical technology is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product will fail to demonstrate adequate efficacy or clinical utility. Investors should evaluate an investment in us in light of the uncertainties typically encountered by developing medical technology companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business, or continue to implement our business plan.

There is substantial doubt about our ability to continue as a going concern.

To date, we have generated limited revenue from product sales and have incurred significant operating losses in each year since our inception and we anticipate that losses may continue for the next several years or until such time as we can generate substantial product revenue and achieve profitability. In connection with the preparation of this Quarterly Report for the three and six months ended June 30, 2022, our management has concluded that there is substantial doubt as to whether we can continue as a going concern for the twelve months following the issuance of this Quarterly Report. Our ability to continue as a going concern is dependent upon raising capital to maintain current operations and continue research and development efforts. We plan to raise additional capital to fund our operations through public or private equity offerings, debt financings, our at-the-market equity offering program, and/or potential new collaborations. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that management of the Company will be able to obtain financing or enter into a collaboration on terms acceptable to the Company.

Based on our current operating plan, even though the 2022 Rights Offering by the Company was fully subscribed, we will not be able to continue as a going concern over the next twelve months unless we raise additional capital by other means. These factors raise substantial doubt about our ability to continue as a going concern.

We can give no assurance that our internal and external sources of liquidity will be sufficient for our cash requirements.

We must have sufficient sources of liquidity to fund our working capital requirements and execute on our strategic initiatives. Future new product launches or investments in other growth initiatives may demand increased working capital before any long-term return is realized from increased revenue. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, and financing opportunities which cannot at all times be assured. Accordingly, there is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plans, pursuing additional financing to the extent available, reducing capital expenditures, suspending certain activities or programs, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity, and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position.

If we are unable to obtain sufficient funding, we may be unable to execute our business plan and fund operations. We may not be able to obtain additional financing on commercially reasonable terms, or at all.

We have experienced operating losses and we may continue to incur operating losses for the next several years as we implement our business plan. Currently, we have no significant revenue from operations and, although we have implemented an at-the-market equity offering program, we do not have arrangements in place for all the anticipated financing that would be required to fully implement our business plan. Our prior losses, combined with expected future losses, have had, and will continue to have, for the foreseeable future, an adverse effect on our stockholders' equity and working capital.

We will need to raise additional capital in order to continue to execute our business plan. If we are unable to raise sufficient additional funds, we will have to scale back our operations. Also, the ongoing hostilities between Russia and Ukraine and the ongoing COVID-19 pandemic and resulting negative impact on the global macroeconomic environment and capital markets may make it more difficult for us to raise additional funds. We may be required to incur debt in the future.

We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. In addition, we believe that we will require additional capital in the future to fully develop and bring to market our technologies and planned products. We have pursued and may pursue additional funding through various financing sources, including the private sale of our equity securities, debt financings, our at-the-market equity offering program, licensing fees for our technology, joint ventures with capital partners, and project type financing. If we raise funds by issuing equity or equity-linked securities, dilution to some or all our stockholders would result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. We also may seek government-based financing, such as development and research grants. There can be no assurance that funds will be available on commercially reasonable terms, if at all.

Any future indebtedness could impose on us restrictive covenants, including, further limitations on our ability to incur additional debt, limitations on our ability to issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. Also, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish, or license to a third party on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or reserve certain opportunities for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may be required to, among other things, delay, scale back or eliminate some or all of our commercial activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business. If any of these things were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited or we may be unable to continue operations, in which case you could lose your entire investment.

Our corporate restructuring and the associated headcount reduction announced in March 2022 may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business.

On March 31, 2022, we announced an approximate 20% reduction in headcount as part of a corporate restructuring plan. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring plan, our operating results and financial condition would be adversely affected. We may have to undertake additional headcount reductions or restructuring activities in the future. Furthermore, our restructuring activities may be disruptive to our operations and could result in material delays in our new product development programs. For example, our headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations, our CellFX System production efforts, servicing of commercial accounts, and product development activities. Our headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, regulatory, manufacturing, and other personnel critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our new product candidates in the future and could also harm our existing and planned commercial activities in dermatology.

Because our business is not profitable, from time to time we may undergo a reduction in force to reduce our operating expenses. However, any corporate restructuring or headcount reduction may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business.

If we decide to reduce headcount to lower our operating expenses, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from such a restructuring because of unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from such a restructuring, our operating results and financial condition would be adversely affected. Any restructuring activities would be disruptive to our operations and could result in material delays in our new product development programs. For example, headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations. Headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, regulatory, manufacturing, and other personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our new product candidates in the future and could also harm our existing and planned commercial activities in dermatology.

Our revenues and future profitability are entirely dependent upon one family of products, the CellFX System, and one platform technology, Nano-pulse Stimulation.

Our revenue is generated entirely from the CellFX System, which consists of a console, handpieces and tips, and both these products and all our potential products under development are based upon the same patented platform technology, Nano-pulse Stimulation (“NPS”). Our revenue is therefore dependent on the success of these products and platform technology, and if these products are not widely adopted by dermatologists or if we suffer any disruptions in our ability to sell these products, our business will suffer. Reliance on a single family of products and single platform technology could negatively affect our results of operations and financial condition. Our ability to become profitable will depend upon the commercial success of these products and platform technology.

We market the CellFX System primarily to aesthetic and medical dermatologists who may be slow or fail to adopt our products or who may use our products in only a small percentage of their eligible patients for a variety of reasons, including, among others:

- lack of experience with our products;
- lack of adequate reimbursement or cost to the patient;
- lack of conviction regarding evidence supporting cost benefits or cost effectiveness of our products over existing alternatives;
- lack of clinical data showing longer-term patient benefits;
- the possible introduction of new technologies competitive to our products; and

liability risks generally associated with the use of new products and procedures.

Moreover, our products, including our platform NPS technology, could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including but not limited to:

entrance of new competitors into our markets;

technological advancements of alternative technologies, such as laser ablation technologies;

loss of key relationships with suppliers, group purchasing organizations, or end-user customers;

manufacturing or supply interruptions;

product liability claims;

our reputation and product market acceptance;

loss of existing regulatory approvals or the imposition of new requirements to maintain such approvals; and

product recalls or safety alerts.

We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause our stock price to decline.

The Company may provide financial guidance about its business and future operating results. In developing this guidance, the Company's management must make certain assumptions and judgments about its future operating performance, including but not limited to projected hiring of sales professionals, growth of revenue in the aesthetic device market, increase or decrease of its market share, costs of production of its recently introduced products, and stability of the macro-economic environment in the Company's key markets. Furthermore, analysts and investors may develop and publish their own projections of the Company's business, which may form a consensus about the Company's future performance. The Company's business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of the Company's control, and which could adversely affect its operations and operating results. Furthermore, if the Company makes downward revisions of its own previously announced guidance, or if the Company's publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of the Company's common stock could decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

the timing and cost of, and level of investment in, research, development, and commercialization activities relating to our product and product candidates, which may change from time to time;

the timing of receipt of approvals or clearances for our product candidates from regulatory authorities in the United States or internationally;

the timing and status of enrollment for our clinical trials;

coverage and reimbursement policies with respect to our product and product candidates, including the degree to which procedures using our products are covered and receive adequate reimbursement from third-party payors, and potential future drugs or devices that compete with our products;

the costs of manufacturing our product, as well as building out our supply chain, which may vary depending on the quantity of production and which will vary significantly depending upon the terms of our agreements with manufacturers;

expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;

the level of demand for our product and any product candidates, if approved or cleared, which may vary significantly over time;

litigation, including patent, employment, securities class action, stockholder derivative, general commercial, and other lawsuits;

future accounting pronouncements or changes in our accounting policies; and

the timing and success or failure of nonclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met our previously publicly stated revenue or earnings guidance.

Because we operate in a highly competitive market, we can expect to face competition from large, well-established manufacturers of medical technologies, devices and similar products; we may not be able to compete effectively against companies with significantly more resources.

The medical technology, medical device, biotechnology, and pharmaceutical industries are characterized by intense and dynamic competition to develop new technologies and proprietary therapies. We face competition from a number of sources, such as pharmaceutical companies, medical device companies, generic drug companies, biotechnology companies, and academic and research institutions. We may find ourselves in competition with companies that have competitive advantages over us, such as:

significantly greater name recognition;

established relationships with healthcare professionals, customers, and third-party payers;

competitive products with greater efficacy or better safety profiles;

established distribution networks;

additional lines of products and the ability to offer rebates, higher discounts, or incentives to gain a competitive advantage;

greater experience in obtaining patents and regulatory approvals for product candidates;

greater experience conducting new product research and development, manufacturing therapies, conducting clinical trials, obtaining regulatory approval for products, and marketing approved products; and

greater financial and human resources for product development, sales and marketing.

We may also face increased competition in the future as new companies enter our markets and as scientific developments surrounding electro-signaling therapeutics continue to accelerate. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us. In addition, certain of our product candidates may compete with other dermatological products, including over the counter ("OTC") treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices. Even if a generic product or an OTC product is less effective than our product candidates, a less effective generic or OTC product may be more quickly adopted by physicians and patients than our competing product candidates based upon cost or convenience. As a result, we may not be able to compete effectively against current and potential future competitors or their devices and products.

We may rely on third parties for our sales, marketing, manufacturing, and/or distribution activities, and these third parties may not perform satisfactorily.

To be able to commercialize our products and planned products, we may elect to internally develop aspects of sales, marketing, large-scale manufacturing, or distribution, or we may elect to use third parties with respect to one or more of these functions. Our reliance on these third parties may reduce our control over these functions; however, reliance on third parties does not relieve us of our responsibility to ensure compliance with all required legal, regulatory, and scientific standards. These third parties may also be adversely impacted by COVID-19 which could affect their ability to perform satisfactorily. Any failure of these third parties to perform satisfactorily and in compliance with relevant laws and regulations could lead to delays in the development of our products or planned products, including delays in our clinical trials, or failure to obtain necessary regulatory approvals, or failure to successfully commercialize our products or other future products. Some of these events could be the basis for FDA or other regulatory action, including injunction, recall, seizure, or total or partial suspension of production.

We have recently commenced revenue-producing operations; however, we may be unsuccessful in earning significant revenues. We believe that developing the commercialization aspects of a company will take a substantial amount of capital and commitment of time and effort. We may seek development and marketing partners and license our technology to others in order to avoid our having to provide the marketing, manufacturing, and distribution capabilities within our organization. There can be no assurance that we will find any development and marketing partners or companies that are interested in licensing our technology. If we are unable to establish and maintain adequate sales, marketing, manufacturing, and distribution capabilities, independently or with others, we will not be able to generate product revenue, and may not become profitable.

If we lose key management personnel, our ability to identify, develop and commercialize new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

We are highly dependent upon the principal members of our management team, including our Chief Executive Officer, Darrin Uecker, and members of our finance, sales, marketing, scientific, and engineering teams. These persons have significant experience and knowledge with sub-microsecond pulsed electric fields and more broadly in aesthetics, dermatology, life sciences, and medical technologies. The loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. The loss of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy. We compete for qualified management and scientific personnel with other life science companies, academic institutions, and research institutions. Our employees could leave our Company with little or no prior notice. They are free to work for a competitor. If one or more of our senior executives or other key personnel were unable or unwilling to continue in their present positions, we may not be able to replace them easily or at all, and other senior management may be required to divert attention from other aspects of the business. In addition, we do not have "key person" life insurance policies covering any member of our management team or other key personnel. The loss of any of these individuals or any inability to attract or retain qualified personnel, including scientists, engineers, and others, could prevent us from pursuing collaborations and materially and adversely affect our product development and introductions, business growth prospects, results of operations, and financial condition.

There is a limited talent pool of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory, and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge we require and the intense competition that exists for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

We have very limited experience selling the CellFX System.

Successfully commercializing medical devices such as ours is a complex and uncertain process. We began marketing and selling the CellFX System in the United States, Canada, and certain limited European markets in late 2021 to dermatologists through a limited direct sales force. In January 2022, we established an operating company in the Netherlands to further enhance our operations in Europe. As of June 30, 2022, our U.S. sales force consisted of 5 sales managers and directors and 6 clinical support specialists directly employed by us. As of June 30, 2022, our international sales force consisted of 5 sales managers and directors and 6 clinical support specialists, all of whom are employed by Globalization Partners, a third-party employer of record engaged by us. We therefore have limited experience marketing and selling the CellFX System and our revenues and cash flows have been volatile and difficult to predict.

We hire and train sales representatives and clinical specialists with backgrounds and experience in the aesthetic dermatology market, especially those familiar with energy-based therapies and who have existing relationships with dermatologist. However, we expect that our sales force will require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us.

Our commercialization efforts depend on the efforts of our management and sales team, our third-party manufacturers and suppliers, physicians and medical clinics, and general economic conditions, among other factors, including the following:

- the effectiveness of our marketing and sales efforts in the United States and internationally;
- our success in educating physicians and patients about the benefits, administration and use of our products;
- the acceptance by physicians and patients of the safety and effectiveness of our products;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing therapies;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to our CellFX System;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products; and
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our products.

Our intention is for our direct sales representatives to develop long-lasting relationships with the dermatologists they serve. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives with significant technical knowledge in various areas, such as dermatology and ablation technologies. New hires require training and take time to achieve full productivity. Additionally, we have experienced significant turnover in our commercial team since the beginning of 2022, partly because of the reduction in force announced in March 2022. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. Also, if our direct sales representatives or third-party distributors fail to adequately promote, market and sell our products or decide to leave or cease to do business with us, our sales could significantly decrease or grow at a rate too slow to become profitable. In addition, our future sales will largely depend on our ability to increase our marketing efforts and adequately address our customers' needs. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and we may not generate sufficient revenue to become profitable. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations, and financial condition.

Rapidly changing technology in life sciences could make the products we are developing obsolete.

The life sciences industries are characterized by rapid and significant technological changes, frequent new product introductions and enhancements, and evolving industry standards. Our future success will depend on our ability to continually develop and then improve the products that we design and to develop and introduce new products that address the evolving needs of our customers on a timely and cost-effective basis. Also, we will need to pursue new market opportunities that develop as a result of technological and scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand. Any new products developed by us may not be accepted in the intended markets. Our inability to gain market acceptance of new products could harm our future operating results.

If we are unable to manage rapid growth of our business, our future revenue and operating results may be harmed.

From the time, we have experienced rapid growth in our business. Any rapid growth imposes significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could mean that fewer experienced people carry out our research and development activities, manufacture, market, and sell CellFX Systems and NPS therapies and procedures, which could result in inefficiencies and unanticipated costs, reduced quality, and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure, and the failure to continue to upgrade our technical, administrative, operating, and financial control systems, or the occurrence of other unexpected expansion difficulties, could have a material adverse effect on our business, financial condition and results of operations, and our ability to timely execute our business plan. During periods of rapid growth, we may be unable to maintain the quality of, or delivery timelines of, our products or satisfy worldwide customer demand. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business. We cannot guarantee that any of the personnel, systems, procedures, and controls we put in place will be adequate to support the manufacture and distribution of our products. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

We must successfully educate and train dermatologists and their staff on the proper use of the CellFX System.

Although most dermatologists may have adequate knowledge on how to use our novel CellFX System based on their clinical training and experience, we believe that the most effective way to introduce and build market demand for our products is by directly training dermatologists in the use of our products. Convincing dermatologists to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will succeed in these efforts. If dermatologists are not properly trained, they may not use our products and, as a result, we may not maintain or grow our sales or achieve or sustain profitability. If dermatologists are not properly trained, they may also misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against us, any of which could have a significant adverse effect on our business, financial condition and results of operations.

Additionally, our strategy includes educating key opinion leaders in the industry. If these key opinion leaders determine that alternative technologies are more effective or that the benefits offered by our products are not sufficient to justify their higher cost, or if we encounter difficulty promoting adoption or establishing these systems as a standard of care, our ability to achieve market acceptance of the products we introduce could be significantly limited.

Although we believe our training methods for dermatologists are conducted in compliance with FDA and other applicable regulations developed both nationally and in other countries, if the FDA or other regulatory agency determines that our training constitutes promotion of an unapproved use or promotion of an intended purpose not covered by the CE mark affixed to our products or FDA approved labeling, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine, or criminal penalty.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and place orders with suppliers based on our estimates of future demand for our products. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to adequately manage our expansion efforts, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast customer acceptance of new product enhancements, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Similarly, a portion of our inventory could become obsolete or expire, which could have a material and adverse effect on our earnings and cash flows due to the resulting costs associated with inventory impairment charges and costs required to replace obsolete inventory. Any of these occurrences could negatively impact our financial performance.

Conversely, if we underestimate customer demand for our products, we may not be able to deliver sufficient products to meet our customers' requirements, which could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or our third-party manufacturers may not be able to allocate sufficient resources to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

We have limited experience in manufacturing our products in large-scale commercial quantities and we may face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results.

Our success depends, in part, on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet demand, while adhering to product quality standards, complying with regulatory quality system requirements, and managing manufacturing costs. We have a manufacturing facility located in Hayward, California where we produce, package and warehouse the CellFX System. We also rely on third-party manufacturers for production of some of the components used in the CellFX System. If our facility, or the facilities of our third-party contract manufacturers, suffer damage, or a force majeure event, this could materially impact our ability to operate.

We are also subject to other risks relating to our manufacturing capabilities, including:

quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, some of whom are our single-source suppliers for the products they supply;

failure to secure raw materials, components and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;

inability to secure raw materials, components and materials of sufficient quality to meet the exacting needs of medical device manufacturing;

failure to maintain compliance with quality system requirements or pass regulatory quality inspections;

inability to increase production capacity or volumes to meet demand; and

inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements.

Certain parts used in the manufacturing of our equipment may experience shortages in global supply which could impact our ability to manufacture our device for customers or maintain research and development timelines.

There are several component parts used in the manufacture of our device that are used by many manufacturers in a variety of products. We will compete with other manufacturers for the supply of these components. Additionally, certain parts that are currently in our design may be discontinued by our suppliers requiring us to find alternative parts. This issue may require us to change the design of our device or purchase significant inventories of these parts in order to protect against manufacturing delays. We may not be able to procure alternative components or adequate raw material inventories which would result in an inability to produce our device.

As our international sales and operations grow, we could become increasingly subject to additional economic, political, and other risks that could harm our business.

We have sales and operations both inside and outside the United States, including a limited sales and marketing organization outside the United States. Our short-term international sales strategy is to increase our presence in Europe and Canada. To successfully market and sell our products in markets outside of the United States, we must address many international business risks with which we have limited experience, and failure to manage these risks may adversely affect our operating results and financial condition. These risks include:

the impact of recessions and other economic conditions in economies, including impact of COVID-19 pandemic, outside the United States;

instability of foreign economic, political and labor conditions;

unfavorable labor regulations applicable to our European operations, such as severance and the unenforceability of non-competition agreements in the European Union;

difficulties in complying with restrictions imposed by regulatory or market requirements, tariffs, or other trade barriers or by U.S. export laws;

potentially adverse tax consequences, including, if required or applicable, difficulties transferring funds generated in non-U.S. jurisdictions to the United States in a tax efficient manner;

difficulties in protecting intellectual property, especially in international jurisdictions;

foreign certification and regulatory clearance or approval requirements;

difficulties in developing effective marketing campaigns in unfamiliar foreign countries;

customs clearance and shipping delays;

difficulties in managing international operations; and

burdens of complying with a wide variety of foreign laws.

Our success depends, in part, on our ability to anticipate and address these and any new risks. We cannot guarantee that these or other factors will not adversely affect our business or operating results.

We could be negatively impacted by actual or perceived violations of applicable anti-corruption law or our own internal policies designed to ensure ethical business practices.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, or FCPA, and similar anti-bribery laws in non-U.S. jurisdictions, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union, and other governments and organizations.

Anti-corruption laws, such as the FCPA and the U.K. Anti-Bribery Act, generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Numerous other laws restrict, and in some cases prohibit, U.S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices and effecting product registrations in foreign countries. Compliance with these regulations is costly.

We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti-corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. Although we have implemented company policies requiring our employees and consultants to comply with the FCPA and similar laws, such policies may not be effective at preventing all potential FCPA or other violations. There can be no assurance that none of our employees and agents, or those companies to which we outsource certain portions of our business operations, will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible. Our development of infrastructure designed to identify anti-corruption matters and monitor compliance is at an early stage. If we are not in compliance with these laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, and liquidity. Likewise, any investigation of any potential violations of these laws by respective government bodies could also have an adverse impact on our reputation, our business, results of operations, and financial condition.

We are subject to laws and regulations relating to personally identifiable health information, and other sensitive information. Security breaches, loss of data and other disruptions to us or our third-party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, both we and our third-party service providers may collect and store sensitive data, including legally protected health information, personally identifiable information about our patients, information related to our trials, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data using a combination of on-site and vendor-owned systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access to data, data corruption, unauthorized disclosure of data, and unauthorized access of data, as well as risks associated with our ability to identify and audit such events.

Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, or those of our vendors, may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we believe we have not experienced any such attack or breach, both we and our vendors may be unable to anticipate attacks, to implement adequate preventative or mitigation measures, to identify any attacks or incidents on a timely basis, or to remediate or otherwise address any attacks or incidents in a timely manner. If any such attack or other incident were to occur, our systems and networks would be compromised and the information we store on those systems and networks could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in a loss of intellectual property protection, legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and the California Consumer Privacy Act of 2018 ("CCPA"), or regulatory penalties, and could require substantial efforts to remediate and otherwise respond to the incident. The CCPA requires covered companies to, among other things, make certain enhanced disclosures related to California residents regarding our use or disclosure of their personal information, allow California residents to opt out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our noncompliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Certain aspects of the CCPA and its interpretation remain uncertain, and we may need to modify our policies or practices in an effort to comply with it. Moreover, in November 2020, California voters approved a new privacy law, the California Privacy Rights Act ("CPRA"), which significantly modifies the CCPA, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Most of the substantive provisions of the CPRA will not take effect until January 2023, however.

Unauthorized access, loss or dissemination of data could also disrupt our operations, including our ability to process tests, provide test results, provide services, conduct research and development activities, collect, process and prepare company financial information, provide information about our product candidates and manage the administrative aspects of our business and could damage our reputation, any of which could adversely affect our business. We cannot be certain that our insurance coverage will be adequate for data handling or data security liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any future claim will not be excluded or otherwise be denied coverage by any insurer. The successful assertion of one or more claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results and reputation.

In addition, the interpretation and application of federal and state consumer, health-related and data protection laws in the United States and internationally are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is, or alleged to be, inconsistent with our practices. If so, this could result in regulatory investigations and enforcement actions, private litigation, claims for damages, and government-imposed fines or orders requiring that we change our practices, any of which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

We are subject to environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business.

We are subject to a variety of local, state, federal, and foreign government regulations relating to the storage, discharge, handling, emission, generation, manufacture, and disposal of toxic or other hazardous substances used in the manufacture of our products. The failure to comply with past, present or future laws could result in the imposition of fines, third-party property damage and personal injury claims, investigation and remediation costs, the suspension of production, or a cessation of operations. We also expect that our operations will be affected by other new environmental and health and safety laws on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws, they will likely result in additional costs, and may require us to change how we manufacture our products, which could have a material adverse effect on our business.

We may fail to meet expectations relating to environmental, social and governance factors.

Market participants, including investors, analysts, customers, and other key stakeholders are increasingly focused on environmental, social and governance ("ESG") factors. We have never had a comprehensive ESG initiative at the Company. Moreover, the ESG factors by which companies' corporate responsibility practices are assessed differ among market participants, are constantly evolving and could result in greater expectations of us and/or cause us to undertake costly initiatives to satisfy such new criteria. We risk damage to our brand and reputation if our corporate responsibility procedures or standards do not meet the standards expected by us. Furthermore, we could fail, or be perceived to fail, in our achievement of any ESG initiatives or goals we may establish in the future and we could also be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors and other key stakeholders or our initiatives are not executed as planned, our reputation and financial results could be materially and adversely affected.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of our product or any future products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our product and the future sale of planned products and the use of these in human clinical studies. For example, we may be sued if our product or any of our product candidates, including any that are developed in combination therapies, allegedly causes injury, or is found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. If we cannot successfully defend ourselves against claims that our product or planned products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, among other things:

decreased demand for our product or any planned products that we may develop;

injury to our reputation and significant negative media attention;

withdrawal of patients from our clinical studies or cancellation of studies;

significant costs to defend the related litigation and distraction to our management team;

substantial monetary awards to patients;

loss of revenue; and

the inability to commercialize any future products that we may develop.

For example, during the course of treatment, patients may suffer adverse events for reasons that may or may not be related to the CellFX System or our NPS technology. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact, or end our opportunity to receive or maintain regulatory approval to market those products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval processes, or impact and limit the type of regulatory approvals our products could receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could harm our business.

We currently maintain product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

We have incurred net losses since our inception and anticipate that we may continue to incur significant losses for the foreseeable future. If not utilized, some of our federal and state net operating losses ("NOLs") carryforwards will begin to expire in various years beginning after 2034. Under the Internal Revenue Code of 1986, as amended, or the Code, and certain similar state tax provisions, we are generally allowed to carry forward our NOLs from a prior taxable year to offset our future taxable income, if any, until such NOLs are used or expire, subject to certain limitations. The same is true of other unused tax attributes, such as tax credits.

In addition, under Section 382 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We believe that we have had one or more ownership changes, and, as a result, a portion of our existing NOLs may be subject to limitation. Future changes in our stock ownership could result in additional limitations. We may not be able to utilize a material portion of our NOLs even if we attain profitability.

We have a substantial amount of goodwill and intangible assets which over time may have to be written down as we make the required periodic assessments as to their value as reflected in our financial statements.

A significant portion of our total assets are comprised of goodwill and intangibles that arose from our 2014 business acquisitions. We review goodwill for impairment at least annually or whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. We also review our intangible assets for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. If we take an impairment charge for either goodwill or intangible assets, the overall assets will be reduced. Such an impairment charge may result in a change in the perceived value of the Company and ultimately may be reflected as a reduction in the market price of our securities. Additionally, an impairment charge may also adversely influence our ability to raise capital in the future.

Risks Related to Product Development

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. For example, success in nonclinical studies and early feasibility clinical studies does not ensure that the expanded clinical trials needed to support regulatory submissions will be successful. Setbacks can be caused by, among other things, nonclinical findings made while clinical trials are underway, safety or efficacy observations made in clinical trials, including previously unreported adverse events, or post-approval observations. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval or clearance for our product candidates or to expand the existing approvals or clearances for our existing products.

Our long-term growth depends on our ability to commercialize our products in development and to develop and commercialize additional products through our research and development efforts, and if we fail to do so we may be unable to compete effectively.

The medical device industry is characterized by intense competition, rapid technological changes, new product introductions and enhancements, and evolving industry standards. Our business prospects depend in part on our ability to develop and commercialize new products and applications for our NPS technology, including in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our products in the dermatology market. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as physician, hospital, and healthcare provider practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

We might be unable to successfully commercialize our current products with domestic or international regulatory clearances or approvals or develop or obtain regulatory clearances or approvals to market new products. Additionally, these products and any future products might not be accepted by dermatologists or other health care workers or the third-party payors who reimburse for the procedures performed with our products or may not be successfully commercialized due to other factors. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate clinician and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

If we do not develop and obtain regulatory clearances or approvals for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material, or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Interim "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may announce are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

If we fail to maintain necessary regulatory clearance for our product, or if clearances or approvals for future devices and indications are delayed or not issued, our commercial operations would be harmed.

Our product candidates under development are medical devices that are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- device design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, and storage;
- premarketing clearance or approval;
- record keeping;
- device marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing device, can be marketed in the United States, the device's manufacturer must first submit and receive either 510(k) clearance or Premarket Approval ("PMA") from the FDA, unless an exemption applies. In the 510(k)-clearance process, the FDA will determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate reasonable safety and effectiveness of the device based on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Either process can be expensive, lengthy and unpredictable.

Any failure to obtain further 510(k) clearances may add significant time and expense to our regulatory clearance process, may delay our ability to generate revenue, and may have a negative impact on our stock price. We may not be able to obtain the necessary clearances or approvals necessary to market the CellFX System for specific indications or such approvals or clearances may be unduly delayed, which could harm our business. If the FDA rejects our 510(k) submissions for specific indications, we may be required to obtain FDA approval through the de novo pathway, which will require additional time and resources, including the need to conduct more clinical studies to demonstrate safety and effectiveness of our candidate device.

The FDA may not approve or clear our 510(k), de novo, or PMA applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business operations and financial condition. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other action which may prevent or delay approval or clearance of our products under development. Any of these actions could have a material adverse effect on our business operations and financial condition.

The FDA and the U.S. Federal Trade Commission ("FTC") also regulate the advertising and promotion of our devices to ensure that the claims we make are consistent with our regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or the FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including FDA warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

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

adverse publicity, warning letters, fines, injunctions, consent decrees, and civil penalties;

obligations to repair, replace, refund, or recall our marketed devices, or government seizure of them;

operating restrictions, partial suspension, or total shutdown of production;

refusing our requests for 510(k) clearance or premarket approval of new devices, new intended uses or modifications to existing devices;

withdrawing 510(k) clearance or premarket approvals that have already been granted; and

criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

The mechanism of action of NPS technology platform has not been fully determined or validated.

The exact mechanism(s) of action(s) of the NPS technology platform is not fully understood, and data are still being gathered regarding its use. Furthermore, there are only a relatively small number of scientists and researchers who can be considered experts in the use of this emerging technology. Insofar as potential regulators, partners or investors value a clear understanding of a technology's mechanism of action, this limitation could make it more challenging for us to obtain requisite regulatory approvals, investments or a partnership on favorable terms as a result.

Our product and any future product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial desirability or result in significant negative consequences.

The risk of failure of clinical development is high. For example, the vast majority of our in vivo data has been a result of animal testing, and we have only completed a limited number of feasibility studies in humans. Undesirable side effects caused by the CellFX System, NPS pulses, or any of our planned future products could cause us or regulatory authorities to interrupt, delay or halt clinical trials or to revoke previously granted regulatory approvals. Undesirable side effects could also result in more restrictive labeling requirements or the delay or denial of regulatory approval of planned future products by the FDA or other comparable foreign regulatory authority.

Additionally, if we or others identify undesirable side effects caused by the CellFX System, a number of potentially significant negative consequences could result, including:

we may be forced to recall such product and suspend the marketing of such product;

regulatory authorities may withdraw their approvals of such product;

regulatory authorities may require additional warnings on the label and/or narrow the indication of use for the product which could diminish the usage or otherwise limit the commercial success of such product;

the FDA or other regulatory authorities may issue safety alerts, “Dear Healthcare Provider” letters, press releases, or other communications containing warnings about such product;

the FDA may restrict distribution of our product and impose burdensome implementation requirements on us;

we may be required to change the way the product is administered or conduct additional clinical trials;

we could be sued and held liable for harm caused to subjects or patients; and

our reputation could suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the CellFX System or of any future particular planned product, if approved.

Our business is dependent upon physicians adopting the CellFX System and NPS technology, and if we fail to obtain broad adoption, our business would be adversely affected.

Our success depends on our ability to educate physicians regarding the benefits of CellFX procedures over existing treatment modalities and to persuade them to prescribe CellFX procedures for their patients. We do not know if the CellFX System or NPS technology will be successful over the long term, and market acceptance may be hindered if physicians are not presented with compelling data demonstrating the efficacy and safety of our products compared to alternative treatments. Any studies we, or third parties, may conduct comparing the CellFX System or NPS technology with alternative treatments may be expensive, time consuming or may not yield positive results. Additionally, adoption will be directly influenced by a number of financial factors, including the ability of providers to use the CellFX System profitably and to attract cash payments from patients or to obtain sufficient reimbursement from third-party commercial payors and from the Centers for Medicare & Medicaid Services (“CMS”) for the professional services they provide in administering CellFX procedures. The efficacy, safety, performance, and cost-effectiveness of the CellFX System, NPS technology, or other potential products based on NPS technology, on a stand-alone basis and relative to competing services, will determine the availability and level of reimbursement received by us and providers. If physicians do not adopt and prescribe the CellFX System or future products using our NPS technology, we may never become profitable.

We may find it difficult to enroll patients in our clinical trials. If we cannot enroll a sufficient number of eligible patients to participate in our clinical trials, we may not be able to initiate or continue them, which could delay or prevent development of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. In general, if patients are unwilling to participate in our trials because of negative publicity from adverse events in the health care industry or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval or clearance of planned products may be delayed. If there are delays in accumulating the required patients and patient data, there may be delays in completing the trial. Further, if any of our clinical trial sites fail to comply with required good clinical practices, we may be unable to use the data gathered at those sites. Also, if our clinical investigators fail to carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be delayed, suspended, or terminated. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether, and delays in obtaining regulatory authorization for our products.

Laboratory conditions differ from commercial conditions and field conditions, and the safety and effectiveness of our product candidates may depend on the technique of the user.

Observations and developments that may be achievable under laboratory circumstances may not be able to be replicated in broader research and development phases, in commercial settings, or in the use of any of any product or product candidates in the field. Furthermore, CellFX procedures will be administered by healthcare professionals and will require a degree of training and practice to administer correctly. Treatment results achieved in the laboratory or in clinical trials conducted by us or by other investigators may not be representative of the results actually encountered during commercial use of our products due to variability in administration technique. The training and skills of investigators in our clinical trials may not be representative of the training and skills of future product users, which could negatively affect treatment results and the reputation of the Company or its products. In addition, there may be a selection bias in the patients and/or sites of administration chosen for any clinical trials that would positively affect treatment results that may not be representative or predictive of real-world experience with our products, including the CellFX System.

Issues with our firmware and software may negatively affect the function of our devices.

The safety and effectiveness of CellFX procedures and therapies may depend, in part, on the function of firmware run by the microprocessors embedded in the device and associated software. This firmware and software is proprietary to us. While we have made efforts to test the firmware and software extensively, both are potentially subject to malfunction which in turn may harm patients. Further, our proprietary firmware and software may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, data breaches, or similar problems. Any of these might result in harm to patients or the unauthorized release of confidential medical, business or other information belonging to us or to other persons.

We may encounter manufacturing problems or delays that could result in lost revenue. Additionally, we currently rely on third-party suppliers for critical materials needed to manufacture the CellFX System and related applicators. Any problems experienced by these suppliers could result in a delay or interruption of their supply to us and, as a result, we may face delays in the development and commercialization of products.

We are in the process of commencing commercial-scale manufacturing of our product, and we currently rely upon third-party suppliers to manufacture and supply components for the CellFX System. We perform final assembly of our devices at our facility in California. We believe we have an adequate inventory of materials and manufacturing capacity to support all our anticipated commercial launch activities and foreseeable commercial activities. However, if demand for our product increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. The manufacture of the CellFX components in compliance with the FDA's regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with applicable regulations, both foreign and domestic.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with applicable regulatory requirements, and if our contract manufacturers cannot successfully manufacture the components needed for our product in a manner that conforms to our specifications and these strict regulatory requirements, we may not be able to rely on their manufacturing facilities for the manufacture of our product. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our components or if such facilities are subject to enforcement action in the future or are otherwise inadequate with respect to complying with applicable regulatory requirements, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop and market our product or to obtain regulatory approval or clearance for our product candidates.

We currently purchase components for the CellFX System under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers and we may not be able to secure alternative suppliers on favorable terms, or at all. Also, any number of our suppliers may be adversely impacted by COVID-19 which could affect their ability to perform satisfactorily. Any failure of these suppliers to perform satisfactorily could adversely impact our business and results of operations and we may experience delays in manufacturing of our devices while finding another acceptable supplier.

We may not become commercially viable if our ultimate commercialized products or related treatments fail to obtain an adequate level of reimbursement by Medicare and other third-party payers.

We believe that the commercial viability of the CellFX System and any potential devices and products and related treatments, and therefore our commercial success as a company, may be affected by the availability of government reimbursement and medical insurance coverage and reimbursement for newly approved medical therapies, technologies, and devices. Insurance coverage and reimbursement are not assured. It typically takes a period of use in the marketplace before coverage and reimbursement are granted, if it is granted at all. In the United States and in many other jurisdictions, physicians and other healthcare providers generally rely on insurance coverage and reimbursement for their revenues, therefore this is an important factor in the overall commercialization plans of a proposed product and whether it will be accepted for use in the marketplace. Without insurance coverage and reimbursement for our planned products, we would expect to earn only diminished revenues, if any revenues are earned.

Medicare, Medicaid, health maintenance organizations, and other third-party payers are increasingly attempting to contain healthcare costs by limiting both the scope of coverage and the level of reimbursement of new medical technologies and products. As a result, they may not cover or provide adequate payment for the use of the CellFX System or planned products in development. In order to obtain satisfactory reimbursement arrangements, we may have to agree to reduce our fee or sales price below what we currently expect to charge customers, which could adversely affect our profit margins. Moreover, each plan may separately require us to provide scientific and clinical support for the use of our products and, as a result, the coverage determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Even if Medicare and other third-party payers decide to cover procedures involving the CellFX System and our proposed devices and products, we cannot be certain that the reimbursement levels will be adequate. Accordingly, even if these products are approved for commercial sale, unless government and other third-party payers provide adequate coverage and reimbursement for our devices and products, some physicians may be discouraged from using them, and our sales would suffer.

Medicare reimburses for medical technologies and products in a variety of ways, depending on where and how the item is used. However, Medicare only provides reimbursement if CMS determines that the item should be covered and that the use of the device or product is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor, a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered, or at the national level by CMS through a national coverage determination. There are statutory provisions intended to facilitate coverage determinations for new technologies, but it is unclear how these new provisions will be implemented, and it is not possible to indicate how they might apply to the CellFX System or to any of our proposed devices and products, as they are still in the development stages. Coverage presupposes that the technology, device, or product has been cleared or approved by the FDA and further, that the coverage will be consistent with the approved intended uses of the device or product as approved or cleared by the FDA, but coverage can be narrower. A coverage determination may be so limited that relatively few patients will qualify for a covered use of a device or product.

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, Medicare coverage determinations for medical devices and products lag behind FDA approval or clearance. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state-by-state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the U.S. Department of Health and Human Services ("HHS"). Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations.

We work with outside scientists and their institutions in developing our product and product candidates. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise, harm our ability to leverage our discovery platforms, or negatively impact our clinical trials.

We work with scientific advisors and collaborators at academic research institutions in connection with our product development efforts. These scientists and collaborators are not our employees, but they serve as either independent contractors or researchers under research agreements that we have with their sponsoring clinic, academic institution or research institution. These scientists and collaborators may have other commitments limiting their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which could cause competitive harm to our business. To the extent these scientists and collaborators, including those assisting us with our clinical trials, may receive cash or equity compensation in connection with such services from time to time, these relationships and any related compensation may result in perceived or actual conflicts of interest, or cause a regulatory authority to conclude that the financial relationship may have affected the interpretation of the trial, such that the integrity of the data generated by them or by their institutions may be questioned and the utility of the data itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property, then our financial condition, results of operations and the value of our technology and products could be adversely affected.

Patents and other proprietary rights are essential to our business and our ability to compete effectively with other companies is dependent upon the proprietary nature of our technologies. We also rely upon trade secrets, know-how, continuing technological innovations, and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. Our success will depend in part on the ability of our licensors and us to obtain, to maintain (including making periodic filings and payments) and to enforce patent protection for the licensed intellectual property, in particular, those patents to which we have secured rights. We may not successfully prosecute or continue to prosecute the patent applications which we have licensed. Even if patents are issued in respect of these patent applications, we may fail to maintain these patents or may determine not to pursue litigation against entities that are infringing upon these patents. Without adequate protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could unfavorably affect our competitive business position and harm our business prospects. Even if issued, patents may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products.

Litigation or third-party claims of intellectual property infringement or challenges to the validity of our patents would require us to use resources to protect our technology and may prevent or delay our development, regulatory approval or commercialization of our product candidates.

If we are the target of claims by any third party asserting that our products or intellectual property infringe upon the rights of others, we may be forced to incur substantial expenses or divert substantial employee resources from our business. If successful, such claims could result in our having to pay substantial damages or could prevent us from developing one or more products or product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing, or sales of the product or product candidate that is the subject of the suit.

If we, or our collaborators, experience patent infringement claims, or if we elect to avoid potential claims others may be able to assert, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because of their having greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

Our intellectual property rights will not necessarily provide us with competitive advantages.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing on our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain products many years before we obtain marketing approval for products utilizing such patents, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could harm our business.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets, and know-how. Any involuntary disclosure to, or misappropriation by, third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential and proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require, as a matter of company policy, that all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be improperly disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These confidentiality agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure.

If we are unable to protect the intellectual property used in our products, others may be able to copy our innovations which may impair our ability to compete effectively in our markets.

Evaluating the strength and enforceability of our patents involves complex legal and scientific questions and can be uncertain. Both our patents and patent applications can be challenged by third parties and our patent applications may fail to result in issued patents. Moreover, both our existing and future patents may be too narrow to prevent third parties from developing or designing around our intellectual property and in that event we may lose competitive advantage and our business may suffer.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future product candidates, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

We have not yet registered some of our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Additionally, even if we apply to register our trademarks in all of our potential markets, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

Risks Related to Government Regulation

We are subject to stringent domestic and foreign regulation. Any unfavorable regulatory action or adverse change in law may materially and adversely affect our future financial condition and business operations and prospects.

The CellFX System and any other potential devices and products we develop are, and will continue to be, subject to extensive, rigorous, and ongoing regulation by numerous government agencies, including the FDA and similar foreign regulatory authorities. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our medical technology. The process of obtaining and maintaining marketing approval or clearance from the FDA and similar foreign regulatory authorities for new devices and products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant indeterminate amount of time;
- require the expenditure of substantial resources;
- involve rigorous preclinical and clinical testing, and possibly post-market surveillance;
- involve modifications, repairs or replacements of our products;
- require design changes of our products;
- result in limitations on the indicated uses of our products; and
- result in our never being granted the regulatory approval or clearance we seek.

If we experience any of these occurrences, our operations may suffer and we might experience harm to our competitive standing, which could adversely affect our financial condition.

We are subject to, and will have ongoing responsibilities under, FDA and international regulations, both before and after a product is approved or cleared and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections. If an inspection were to conclude that we are not in compliance with applicable laws or regulations, or that any of our devices are ineffective or pose an unreasonable health risk, the FDA or similar foreign regulatory authorities could ban such devices or products, detain or seize such devices or products, order a recall, repair, replacement, or refund of such devices or products, or require us to notify health professionals and others that the therapies, devices or products present unreasonable risks of substantial harm to the public health. Additionally, the FDA or similar foreign regulatory authorities may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to our devices and products or assess civil or criminal penalties against our officers, employees, or us. The FDA and similar foreign regulatory authorities have been increasing their scrutiny of the industry and governments are expected to continue to scrutinize the industry closely with inspections and possibly enforcement actions. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our devices and products, including the CellFX System. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

The continuing development of the CellFX System and other products depends upon maintaining strong working relationships with physicians.

The development, marketing, and sale of the CellFX System, and any future products in development, depends upon our ability to maintain strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing, and sale of our products. Physicians assist us in clinical trials and as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations. The medical device industry's relationship with physicians is under increasing scrutiny by the Office of Inspector General ("OIG"), the Department of Justice ("DOJ"), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general, and other government agencies, could significantly harm our business, including compromising the use or integrity of our clinical data in regulatory submissions to the FDA or similar regulatory authorities.

We are subject to healthcare and other laws and regulations relating to our business and could face substantial penalties if we are determined not to have fully complied with such laws, which could have an adverse impact on our business.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate applicable laws or regulations. There are many federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval or clearance. Such laws include:

U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can find a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government;

HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

HIPAA, as amended by HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by these physicians and their immediate family members;

the CCPA requires covered companies to, among other things provide new disclosures to California consumers and afford such consumers new abilities to opt-out of certain sales of personal information. We cannot yet predict the impact of the CCPA or the recently approved CPRA on our business or operations, but it may require us to modify our data processing practices and policies and could cause us to incur substantial costs and expenses in an effort to comply;

federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We have implemented compliance related programs and procedures to help identify and deter healthcare and other violations by employees and other third parties that perform services for us. Notwithstanding our efforts, however, it is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable healthcare or other applicable laws. In addition, we are subject to the risk that a person or government could allege violations of such laws, regulations and other obligations, or allege that fraud or other misconduct has taken place, even if no misconduct has occurred. If any such actions are instituted against us, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations if we are not successful in defending ourselves or asserting our rights. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could have a material adverse effect on our liquidity and financial condition.

Also, any material change to any of the laws or regulations applicable to our business could harm our business, financial condition and results of operations.

To obtain the necessary device approvals or clearances from regulatory authorities for our future product candidates, we will have to conduct various preclinical and clinical tests, which may be costly and time consuming, and may not provide results that will allow us to seek regulatory approval or clearance.

The number of preclinical and clinical tests that will be required for regulatory clearance or approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the device, the jurisdiction in which we are seeking approval or clearance and the applicable regulations. Regulatory agencies, including those in the United States, Canada, Europe, and other jurisdictions where medical devices and products are regulated can delay, limit or deny approval of a product for many reasons. For example, regulatory agencies:

may not deem a technology or device to be reasonably safe or effective for any intended use or indication;

may interpret data from preclinical and clinical testing differently than we do;

may determine our manufacturing facility or processes do not comply with quality system regulations;

may conclude that our products do not meet quality standards for durability, long-term reliability, biocompatibility, electromagnetic compatibility, or electrical safety; or

may change their approval or clearance policies or adopt new regulations in a manner that is adverse to us.

These regulators may make requests or disagree with us regarding the design or conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval or clearance on future product candidates, or expanded indications of use for our existing products, and increased costs.

Even if a potential device or product ultimately is cleared or approved by regulatory authorities, it may be cleared or approved only for narrow indications which may render it commercially less viable.

Even if we complete clinical testing and a potential device or product of ours is cleared or approved, it may not be cleared or approved for the indications that are necessary or desirable for a successful commercialization. Regulators may grant marketing authorization contingent on the performance of costly additional clinical trials which may be required after approval or clearance. Regulators also may approve or clear our lead product candidates, including the CellFX System, for a more limited indication or a narrower patient population than we originally requested. Our preference will be to obtain as broad an indication as possible for use in connection with the particular disease or treatment for which it is designed. However, the final indication or labeling may be more limited than we originally seek. Any limitation on use may make the device or product commercially less viable and more difficult, if not impractical, to market. Therefore, we may not obtain the revenues that we seek in respect of the proposed product, and we will not be able to become profitable and provide an investment return to our investors.

We will be subject to ongoing requirements and inspections that could lead to the restriction, suspension or revocation of our clearance.

We, as well as any potential third-party manufacturer, will be required to adhere to FDA quality systems requirements, which include testing, control, and documentation requirements. We will be subject to similar regulations in foreign countries. Even when regulatory approval or clearance of a product is granted, the approval or clearance may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or clearance, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Ongoing compliance with quality system regulations and other applicable regulatory requirements is strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals or clearances previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or clearances, or any other failure to comply with regulatory requirements would limit our ability to operate and could materially increase our costs.

Because we and one of our licensors have used federal funding in the development of certain aspects of our technology, the federal government retains 'march-in' rights in connection with results derived from these grants.

March-in rights give the federal government the right to grant to other entities, which may include competitors, licenses or to take a license for itself if the government funded the development of a patent. The march-in right applies to patents that have been issued. The march-in right is intended to be used only if there is a threat to public health and safety that the owner of the patent is not equipped to handle. The march-in right may also be used to remove the exclusive rights belonging to a patent holder if the patent for which the government provided funding is not suitable for public use. If march-in rights are used by the government, the entities using the patent are required to pay royalties to the patent holder, which amount would be subject to negotiation. Because federal funding was used for some aspects of the Company's technology that will be the subject of some of our patents, the Company could be subject to the march-in right and lose its exclusivity of those patents, and may suffer direct competition if any license is granted by the government under the march-in right to a competitor.

Our employees, collaborators and other personnel may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators and other personnel, which could include intentional, reckless and/or negligent conduct or disclosure that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; or (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws. These laws may impact, among other things, future sales, marketing and education programs. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud and abuse, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the use of information obtained in the course of patient recruitment for clinical trials.

We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent unlawful activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business and financial condition.

Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse effect on us.

Proposals by the federal government, state governments, regulators, and third-party payors to control or manage the increased costs of healthcare and to reform the U.S. healthcare system may impact our business significantly. Certain proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business and financial condition. We cannot predict the initiatives that may be adopted in the future or their full impact on our business. The continuing efforts of governments, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare may negatively impact our ability to set a price that we believe is fair for our products, our ability to generate revenue and achieve profitability, and the availability of capital.

Risks Related to Owning Our Common Stock

The price of our common stock has been, and we expect it to continue to be, highly volatile, and you may be unable to sell your shares at or above the price you paid to acquire them.

The market price of our common stock has been highly volatile, and we expect it to continue to be highly volatile for the foreseeable future in response to many risk factors listed in this section, and others beyond our control, including:

- results of clinical trials of our planned products or those of our competitors;
- actions by regulatory bodies, such as the FDA, that affect our business or have the effect of delaying or rejecting approval or clearance of our planned products;
- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by our customers, partners or suppliers relating directly or indirectly to our products, services or technologies;
- announcements of technological innovations by us or our competitors;
- changes in laws or regulations applicable to the CellFX System or to our planned products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments, or achievement of significant milestones;
- additions or departures of key personnel;
- competition from existing products or new products that may emerge;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters or our ability to obtain intellectual property protection for our technologies;
- actual or alleged security breaches;

announcements or expectations of additional financing efforts;

sales of our common stock by us or our stockholders;

stock price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

reports, guidance and ratings issued by securities or industry analysts;

overall conditions in our industry and market including the negative impact of COVID-19 on the global economy and markets; and

general economic and market conditions.

Any of the above may cause our stock price or trading volume to decline. Stock markets in general, and the market for companies in our industry in particular, have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including ours. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. Investors may not realize any return on their investment in us and may lose some or all of their investment. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. The high volatility of our stock price, the composition of our Board and governance practices, including our Chairman's repeated interest in acquiring additional shares in our Company through related party transactions, as well as countless other factors not identified above, increase the risk of securities litigation or shareholder derivative litigation against the Company and its Directors. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns and adversely impact our ability to raise capital to fund our operations, which could seriously harm our business.

Sales or purchases of shares of our common stock may adversely affect the market for our common stock.

If we or our stockholders, particularly our directors, executive officers and significant stockholders, sell or purchase, register for sale, or indicate an intent to sell or purchase, shares of our common stock in the public market, it may have a material adverse effect on the market price of our common stock. In particular, Robert W. Duggan, our majority stockholder and Board Chairman, is not subject to any contractual restrictions with us on his ability to sell or transfer the shares of our common stock that he holds, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our Company to a third party. Many of Mr. Duggan's shares in the Company have been registered for resale pursuant to an effective registration statement on Form S-3. Sales by Mr. Duggan of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

Additionally, we maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of $160.0 million of our common stock, preferred stock, depositary shares, warrants, debt securities or units. We may also issue shares of common stock or securities convertible into, exchangeable or exercisable for our common stock from time to time in connection with financings, acquisitions, investments, or otherwise. Any such issuances would result in dilution to some or all of our existing stockholders and could cause our stock price to fall. We may also sell shares or other securities at a price per share that is less than the price per share paid by existing investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

We do not know whether an active, liquid and orderly trading market will exist for our common stock and as a result it may be difficult for you to sell your common stock.

Prior to our initial public offering in May 2016, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Capital Market ("Nasdaq"), the market for our shares has demonstrated varying levels of trading activity. As a result of these and other factors, you may not be able to sell your common stock quickly, at or above the price paid to acquire the stock or at all. Further, an inactive market may also harm our ability to raise capital by selling additional common stock and may harm our ability to enter into strategic collaborations or acquire companies or products by using our common stock as consideration.

Concentration of ownership by our principal stockholder limits the ability of others to influence the outcome of director elections and other transactions requiring stockholder approval, or create the potential for conflicts of interest.

A majority percentage of our outstanding stock is held by Robert W. Duggan, Chairman of our Board, who beneficially owns approximately 56% of our common stock outstanding as of the date of this Quarterly Report. As a result, Mr. Duggan has control over corporate actions requiring stockholder approval, including the following actions:

to elect or defeat the election of our directors;

to amend or prevent amendment of our certificate of incorporation or bylaws;

to effect or prevent a merger, sale of assets or other corporate transaction; and

to control the outcome of any other matter submitted to our stockholders for vote.

Mr. Duggan's controlling interest in the Company also creates the potential for conflicts of interest which be viewed unfavorably by minority stockholders, thereby hurting our stock price. For example, in November 2021, we engaged outside legal counsel to represent the Company even though the same legal counsel currently represents Mr. Duggan personally in other matters. This legal counsel represented Mr. Duggan in certain related party transactions described herein and could represent both the Company and Mr. Duggan in future related party transactions. Three of our directors, including Mr. Duggan, are executives at Summit Therapeutics Inc., another company in which Mr. Duggan holds a controlling equity interest. There are no family relationships among any of our directors or executive officers, however, Mr. Duggan and Dr. Zanganeh have a personal relationship with each other.

Additionally, because Mr. Duggan owns a majority of our outstanding shares, we are considered to be a "controlled" company under applicable Nasdaq rules. As such, we may voluntarily elect not to comply with certain of Nasdaq's corporate governance requirements, such as certain rules concerning the setting of executive compensation and the appointment of directors. Accordingly, during the period we remain a controlled company and during any transition period following a time when we are no longer a controlled company, other stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq Stock Market. As a member of our Board, Mr. Duggan will adhere to the corporate governance standards adopted by the Company.

Even though we have not yet elected to take advantage of any of these corporate governance exemptions permitted by Nasdaq, Mr. Duggan's stock ownership and our status as a "controlled" company may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our Company, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock and any such purchases, including purchases of equity securities in connection with any rights offerings or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a larger percentage of our common stock.

Management currently beneficially holds a small percentage of our common stock. Other than their positions as directors or officers, and the restriction on the stockholders being able to call a special meeting limited to holders of 15% or more of the outstanding shares of common stock, our management will not be able to greatly influence corporate actions requiring stockholder approval.

Robert W. Duggan's controlling ownership position may impact our stock price and may deter or prevent efforts by others to acquire us, which could prevent our stockholders from realizing a control premium.

Robert W. Duggan is our Board Chairman, and beneficially owns approximately 56% of our common stock outstanding as of the date of this Quarterly Report. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock, and any such purchases, including purchases of equity securities in connection with any rights offerings or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a majority of our common stock. As a result of Robert W. Duggan's controlling ownership and position as Board Chairman, others may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares. In addition, public speculation regarding Mr. Duggan, as well as our relationship with Mr. Duggan, could cause our stock price to fluctuate.

We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to public company compliance initiatives.

As a public company, listed in the United States, we have incurred and will continue to incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance.

Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel have and will continue to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and, as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act, the Dodd-Frank Act, and rules adopted by the SEC and Nasdaq, will likely result in increased costs to us as we respond to their requirements. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

Furthermore, these and future rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. For example, we determined not to renew our director and officer liability insurance this year due to disproportionately high premiums quoted by insurance companies. Instead, we and Robert W. Duggan, Chairman of our board of directors, have entered into a letter agreement pursuant to which Mr. Duggan has agreed with us to personally provide "Side A" indemnity coverage on substantially the same terms as our prior coverage program for a one-year period. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers.

We are a "smaller reporting company"; we cannot be certain if the applicable reduced disclosure requirements will make our common stock less attractive to investors.

Through the end of 2021, we were an "emerging growth company," as defined in the JOBS Act, and we took advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. While we are no longer an emerging growth company, we still qualify as a "smaller reporting company," as defined in the Exchange Act, and so long as we remain a smaller reporting company, we benefit from and may take advantage of scaled disclosure requirements. We cannot know if investors find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

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

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We currently have only limited analyst coverage of us and there can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our market price would likely decline. If analysts cease coverage of our Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We have not paid dividends in the past and have no plans to pay dividends.

For the foreseeable future, we plan to reinvest all of our earnings, to the extent we have earnings, into our product research and development efforts, so we have no plans to pay any cash dividends with respect to our securities. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on our outstanding common stock.

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

Certain anti-takeover provisions of Delaware law and provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. These provisions could also make it difficult for stockholders to elect directors that are not nominated by the current members of our board of directors or take other corporate actions, including effecting changes in our management. Our certificate of incorporation and bylaws include provisions that:

authorize our board of directors to issue, without further action by the stockholders, up to 50,000,000 shares of preferred stock and up to approximately 500,000,000 shares of authorized but unissued shares of common stock;

require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;

specify that special meetings of our stockholders can be called only by our board of directors, the chairman of our board of directors, any of our officers, or any stockholder holding at least fifteen percent (15%) of the voting power of the capital stock issued and outstanding and entitled to vote;

establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

require the affirmative vote of holders of at least 66 2/3% of the voting power of all the then outstanding shares of our voting stock, voting together as a single class, to amend provisions of our certificate of incorporation or our bylaws;

give our board of directors the ability to amend our bylaws by majority vote; and

provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board, which is responsible for appointing the members of our management. Furthermore, our bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of us, (b) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of us to us or our stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (d) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided that, if and only if the Court of Chancery dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in Delaware. Our bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may discourage lawsuits against us or our directors, officers, and employees. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to engage in certain types of transactions with us.

General Risk Factors

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the negative impact of COVID-19 on the global economy and markets. Furthermore, the market for aesthetic medical treatments may be particularly vulnerable to unfavorable economic conditions. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets, as has recently been the case due to COVID-19. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our lead product, the CellFX System, or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The identification of one or more material weaknesses would preclude a conclusion that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer a “small reporting company.” At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to litigation risk and to investigations by Nasdaq, the stock exchange on which our securities are listed, by the SEC, and by other regulatory authorities, which could require additional financial and management resources.

We may become involved in litigation that may materially adversely affect us.

From time to time, we may be involved in a variety of claims, lawsuits, investigations, or proceedings relating to securities laws, product liability, patent infringement, contract disputes, and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against us. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability and/or require us to change our business practices. Because of the potential risks, expenses and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business, financial condition, results of operations and prospects. See the section entitled "Legal Proceedings" for more detail on our current legal proceedings.

Our business may be adversely affected by health epidemics including the coronavirus pandemic.

The COVID-19 pandemic has resulted in government authorities implementing, from time to time, numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

For most of 2020 and much of both 2021 and 2022, we required, in accordance with local and state guidelines regarding the COVID-19 pandemic, all of our employees to work remotely unless they could not perform their essential functions remotely. We also suspended all non-essential travel for our employees. While many of our employees are accustomed to working remotely or working with other remote employees, much of our workforce has not historically been remote. We continue to monitor the situation and may adjust our current policies as more information and public health guidance becomes available. Operational restrictions as a result of the COVD-19 pandemic could harm our business, financial condition and results of operations.

In addition, our clinical trials may be affected by the continuing COVID-19 pandemic. Site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 pandemic, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Some of our suppliers of certain materials used in the production of the CellFX System are located in areas heavily impacted by COVID-19 which could limit our ability to obtain sufficient materials. COVID-19 has and will continue to adversely affect global economies and financial markets of many countries, resulting in an economic downturn that could affect demand for the CellFX System and other product candidates, if approved, and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change.

Our facilities in California are located near known earthquake faults, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our facilities in Hayward, California are located near known earthquake fault zones and are vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously, or potentially completely, impaired. In addition, the nature of our activities could make it difficult for us to recover from a natural disaster. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

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

During the three-month period ended June 30, 2022, we completed no unregistered sale of our securities, except for the sale of approximately seven million shares of our common stock, in a rights offering, as described in Note 6 of this Quarterly Report.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description
10.1	Indemnification Letter, dated May 27, 2022, by and between Pulse Biosciences, Inc. and Robert W. Duggan
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Chief Executive and Chief Financial Officers pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulse Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in such filing.

Signatures

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

PULSE BIOSCIENCES, INC.

Date: August 10, 2022

By: /s/ Sandra A. Gardiner
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, and Treasurer
(*Principal Financial and Accounting Officer*)

Robert W. Duggan
611 S Fort Harrison Avenue, Suite 306
Clearwater, FL 33756

May 27, 2022

Pulse Biosciences
3957 Point Eden Way
Hayward, California 94545
Attn: Board of Directors

Re: Indemnification of Board of Directors

Dear Directors:

This letter serves as formal agreement as between Robert Duggan (sometimes referred to herein as "Indemnitor"), on one hand, and Pulse Biosciences, Inc. ("Pulse") and its Board of Directors, on the other, with respect to indemnification of Pulse's past, present, and future corporate directors, officers, and employees, among others, for the year May 31, 2022, through May 31, 2023. Reference is made to that expiring program of insurance underwritten as follows: XL Specialty Insurance Company, Policy No. ELU 174984-21; RSUI Indemnity Company, Policy No. HS693321; Ascot Insurance Company, Policy No. MLXS2110000549-01; Allied World Assurance Company (U.S.) Inc., Policy No. 0312-8756; Berkley Insurance Company, Policy No. BPRO8066883; Berkshire Hathaway Specialty Insurance Company, Policy No. 47-EPC-315267-01 (together, the "Expiring Program"). Capitalized terms that are undefined in this letter agreement shall have the meaning as set forth in the Followed Policies (as defined below).

RECITALS

WHEREAS, Pulse has determined that in order to induce directors and other individuals to provide, or continue to provide, services to Pulse, Pulse wishes to provide for the indemnification of, and advancement of expenses to, its directors and officers to the maximum extent permitted by law;

WHEREAS, Pulse in the past has decided to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of the Delaware General Corporation Law, as provided for in Section 8.9 of the Pulse Bylaws;

WHEREAS, Pulse previously purchased $30 million in directors and officers liability insurance limits in a directors and officers insurance program comprised of six stacked policies with $5 million in limits each; and

WHEREAS, Pulse has received a premium quotation of $978,000 of up-front payments (which amount would be higher if Pulse elected to pay monthly or quarterly) to bind new "Side A only" directors and officers liability insurance with policy limits totaling $15 million for the annual period of May 31, 2022, to May 31, 2023.

IT IS NOW AGREED as between Robert Duggan and Pulse and its Board of Directors that:

1. Indemnitor shall advance the defense costs of, and indemnify, any and all individuals who fall within the definition of "Insured Person," as set forth in the Expiring Program primary D&O Policy issued by XL Specialty Insurance Company Policy No. ELU17498-21 ("XL Policy") or the Expiring Program excess Side A DIC Berkley Insurance Company Policy No. BPRO8066883 ("Berkley Policy") (collectively the "Followed Policies"), pursuant to the XL Policy's Insuring Agreements I(A) and I(D) or the Berkeley Policy's Insuring Agreement I and in accordance with the definitions, conditions, exclusions and other terms of the XL Policy or Berkeley Policy, whichever is more favorable to such Insured Person(s), except as expressly provided in Paragraph 4 below. Indemnitor's liability hereunder shall not exceed $15 million in the aggregate under the Followed Policies ("Limit of Liability").

2. Indemnitor shall, or shall cause an entity to be formed by him, to deposit as security for the obligations set forth herein cash and/or marketable securities, including T-bills or other similar government debt obligations (the "Escrow Funds") with a fair market value equal to the Minimum Value (as defined below) into an escrow account (the "Escrow Account"), which funds shall be available to satisfy all obligations under this letter agreement, which will provide coverage to all Insured Persons as set forth in Paragraph 1 above. The Escrow Agent, who may or may not be the Claims Agent (as defined below), will be determined by Indemnitor, subject to the reasonable approval of the Board. Indemnitor, in his sole discretion, and the Board of Directors, by majority vote of its disinterested directors, may appoint a mutually acceptable third-party agent (a "Claims Agent") to act as claims agent to process Claims submitted by any Insured Person pursuant to this agreement to the extent funded by the Escrow Funds. Indemnitor shall have the ability to trade the securities in the Escrow Account, as well as to substitute or replace securities in the escrow account with other securities, so long as any such substitution or replacement does not reduce the value of the escrow account to less than the Minimum Value during the Term (as defined below). Each month the fair market value of the Escrow Account shall be measured, and if above the Minimum Value, any excess may be withdrawn by Indemnitor, in his sole discretion. To the extent the fair market value is below the Minimum Value, any deficiency shall be deposited into the Escrow Account by Indemnitor within five (5) business days following the end of the month. The "Minimum Value" shall mean (a) with respect to cash and government debt, one hundred percent (100%) of the Limit of Liability, and (b) with respect to marketable securities , such securities valued at one hundred twenty percent (120%) of the Limit of Liability, both less any payments made under this letter agreement, including any subsequent revisions and/or amendments. If the Escrow Funds are made up of a combination of both cash and marketable securities, the values of each component of the fund shall be maintained proportionally to preserve the percentages set forth at 2(a) and 2(b) above.

3. For the avoidance of doubt, Indemnitor shall maintain the right to all income generated from the Escrow Account, including but not limited to interest, dividends, realized gains, and unrealized gains; provided, however, that the Minimum Value shall be maintained in the Escrow Account throughout the Term. Indemnitor will have the right to transfer securities, debt instruments, and cash to and from the Escrow Account with board authorization. Indemnitor shall not require Board approval for the substitution or replacement of government debt for other government debt or for cash.

4. The Escrow Funds shall be used to advance defense costs on behalf of, and indemnify, any Insured Person for any Claim, as defined in the Followed Policies, made during the annual period of May 31, 2022, through May 31, 2023, as set forth in Paragraph 1, except that: (a) the period of indemnification shall be as set forth in this paragraph, (b) any claim shall be subject to the Limit of Liability , and (c) the Indemnitor shall have no obligation to offer any Optional Extension Period or other similar period as described in the Followed Policies.

5. The Escrow Funds are not owned or controlled by Pulse and shall not be the property of the estate of Pulse in any bankruptcy or insolvency proceeding, and the parties agree to structure the arrangements with the Escrow Agent and the Claims Agent accordingly.

6. Indemnitor shall be paid a fee by Pulse, to the extent permissible by law, of $978,000 in consideration of the obligations set forth herein, such fee to be due, owing, and collectible on May 31, 2023.

7. At the end of the annual period of May 31, 2022, to May 31, 2023, and after the closing and final resolution of any Claims falling within the terms of this agreement or either of the Followed Policies, but no earlier than July 31, 2023 (the "Term"), all rights to any remaining Escrow Funds shall revert to Indemnitor free and clear.

8. a. *In the event a Claims Agent is appointed*. Any claim by any individual asserting a right to advancement and/or indemnification by Pulse shall continue to be reviewed and determined in the ordinary course as provided for in the Pulse Bylaws, any private indemnity agreements, any other applicable corporate governance documents, and applicable law as well as to the extent provided in the Followed Policies. Any claim by any individual with respect to the rights set forth in this letter agreement shall first be submitted to the Claims Agent, who shall provide its position with respect to such claim to the Indemnitor and to the claimant within five (5) business days. Indemnitor shall then have sole authority to concur or reject the Claims Agent's determination of coverage, and Indemnitor shall provide his position with respect to such claim to the claimant and Claims Agent within fifteen (15) business days of the Indemnitor's receipt of the Claim Agent's determination. To the extent there is any dispute with respect to any determination of coverage by either the Claims Agent and/or Indemnitor, or any other dispute arising out of this letter agreement, such dispute shall be submitted to a neutral third-party arbitrator and resolved via an expedited process. The Indemnitor, the Insured Person or Insured Persons, and the Claims Agent shall agree to and designate a neutral third party and agree to the details of the expedited dispute resolution process. If these parties cannot agree on a dispute resolution process within ten (10) business days of the Indemnitor's determination, they shall submit their dispute to a third-party arbitrator selected by the staff at the San Francisco office of JAMS and to be administered in accordance with JAMS rules, including the Optional Expedited Arbitration Procedures, which rules are incorporated herein by this reference. The determination of the neutral third party (including, for purposes of clarity, any arbitrator selected by the staff at JAMS to the extent applicable) with respect to any dispute shall be binding and non-appealable. The costs of any dispute resolution as set forth herein shall be split evenly between the Company and the Indemnitor.

b. *In the event a Claims Agent is not appointed*. Any claim by any individual asserting a right to advancement and/or indemnification by Pulse shall continue to be reviewed and determined in the ordinary course as provided for in the Pulse Bylaws, any private indemnity agreements, any other applicable corporate governance documents, and applicable law as well as to the extent provided in the Followed Policies. Any claim by any individual with respect to the rights set forth in this letter agreement shall first be submitted to the Indemnitor, who shall provide his position with respect to such claim within ten (10) business days. To the extent there is any dispute with respect to any determination of coverage by Indemnitor, or any other dispute arising out of this letter agreement, such dispute shall be submitted to a neutral third-party arbitrator and resolved via an expedited process. The Indemnitor and the Insured Person or Insured Persons, shall agree to and designate a neutral third party and agree to the details of the expedited dispute resolution process. If these parties cannot agree on a dispute resolution process within ten (10) business days of the Indemnitor's determination, they shall submit their dispute to a third-party arbitrator selected by the staff at the San Francisco office of JAMS and to be administered in accordance with JAMS rules, including the Optional Expedited Arbitration Procedures, which rules are incorporated herein by this reference. The determination of the neutral third party (including, for purposes of clarity, any arbitrator selected by the staff at JAMS to the extent applicable) with respect to any dispute shall be binding and non-

appealable. The costs of any dispute resolution as set forth herein shall be split evenly between the Company and the Indemnitor.

9. Pulse may, in its sole discretion, determine to waive the requirement of Indemnitor establishing an escrow account pursuant to paragraph 2, and instead have Indemnitor satisfy all indemnification obligations due hereunder directly. Any such waiver shall be in writing by a majority of the disinterested directors of Pulse to Indemnitor.

10. The Insured Persons are express third party beneficiaries of this letter agreement and the agreements contemplated hereby, having the right to enforce the warranties, indemnities and other obligations undertaken by Indemnitor herein and therein, as if they were a direct party to this agreement.

11. This agreement can only be amended by a writing signed by the Indemnitor and by a majority of the Company's disinterested directors then in office.

Very truly yours,

Robert Duggan

AGREED AND ACCEPTED

Board of Directors of Pulse Biosciences, Inc.

By:_____
Darrin Uecker, CEO, President & Director

Exhibit 31.1

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

I, Darrin R. Uecker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 of Pulse Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2022

By: /s/ Darrin R. Uecker
Darrin R. Uecker
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Sandra A. Gardiner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 of Pulse Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2022

By: /s/ Sandra A. Gardiner
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Pulse Biosciences, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his 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.

In Witness Whereof, the undersigned have set their hands hereto as of the 10th day of August 2022.

/s/ Darrin R. Uecker
Darrin R. Uecker
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Sandra A. Gardiner
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, and Treasurer
(Principal Financial and Accounting Officer)

This certification is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulse Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this report, irrespective of any general incorporation language contained in such filing.