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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2020

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 001-38815

Soliton, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4729076**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
5304 Ashbrook Drive Houston, Texas	**77081**
(Address of Principal Executive Offices)	(Zip Code)

844-705-4866

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SOLY	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 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 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 [X]

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. [ ]

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SOLY	The Nasdaq Stock Market

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 of the Company's outstanding common stock as of May 12, 2020 was16,943,578.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

SOLITON, INC.
CONDENSED BALANCE SHEETS
(UNAUDITED)

ASSETS	March 31, 2020	December 31, 2019
Current assets:		
Cash and cash equivalents	$ 7,544,526	$ 11,876,425
Restricted cash	200,000	200,000
Total cash	7,744,526	12,076,425
Prepaid expenses and other current assets	913,169	96,310
Total current assets	8,657,695	12,172,735
Property and equipment, net of accumulated depreciation	785,998	847,399
Intangible assets, net of accumulated amortization	98,289	97,556
Other assets	23,283	23,283
Total assets	$ 9,565,265	$ 13,140,973
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 988,721	$ 1,338,262
Accrued and other current liabilities	861,081	1,525,019
Total current liabilities	1,849,802	2,863,281
Deferred rent	1,070	4,282
Total liabilities	1,850,872	2,867,563
Commitments and contingencies (Note 5)		
Stockholders' equity (deficit):		
Common stock, $0.001 par value, 100,000,000 authorized, 16,943,578 shares issued and outstanding at March 31, 2020 and 16,932,184 shares issued and outstanding at December 31, 2019	16,943	16,932
Additional paid-in capital	67,011,324	66,299,849
Accumulated deficit	(59,313,874)	(56,043,371)
Total stockholders' equity	7,714,393	10,273,410
Total liabilities and stockholders' equity	$ 9,565,265	$ 13,140,973

See accompanying notes to the unaudited condensed financial statements

SOLITON, INC.
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended March 31,	
	2020	**2019**
Revenue	$ —	$ —
Operating expenses:		
Research and development	1,220,327	445,402
Sales and marketing	50,950	57,016
Depreciation and amortization	70,767	29,703
General and administrative	1,932,690	1,854,684
Total operating expenses	3,274,734	2,386,805
Loss from operations	(3,274,734)	(2,386,805)
Other (expense) income:		
Interest expense	—	(822,858)
Interest income	4,231	1,318
Total other income (expense)	4,231	(821,540)
Net loss	(3,270,503)	(3,208,345)
Dividend to Series A and B preferred stockholders	—	(160,219)
Net loss attributable to common stockholders	$ (3,270,503)	$ (3,368,564)
Net loss per common share, basic and diluted	$ (0.19)	$ (0.43)
Weighted average number of common shares outstanding, basic and diluted	16,781,210	7,745,378

See accompanying notes to the unaudited condensed financial statements

SOLITON, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(UNAUDITED)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Par			
Balance, December 31, 2019	16,932,184	$ 16,932	$ 66,299,849	$ (56,043,371)	$ 10,273,410
Stock-based compensation	—	—	711,486	—	711,486
Issuance of common shares	11,394	11	(11)	—	—
Net loss	—	—	—	(3,270,503)	(3,270,503)
Balance, March 31, 2020	16,943,578	$ 16,943	$ 67,011,324	$ (59,313,874)	$ 7,714,393

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Par	Shares	Par	Shares	Par			
Balance, December 31, 2018	416,666	$ 417	2,118,100	$ 2,118	1,998,056	$ 1,998	$ 22,568,857	$ (42,131,275)	$ (19,557,885)
Stock-based compensation	—	—	—	—	—	—	512,045	—	512,045
Debt discount on convertible notes and notes payable – issuance of warrants	—	—	—	—	—	—	145,974	—	145,974
Payment of deferred direct issuance costs	—	—	—	—	—	—	(186,029)	—	(186,029)
Issuance of common shares for extinguishment of preferred shares	(416,666)	(417)	(2,118,100)	(2,118)	2,534,766	2,535	—	—	—
Issuance of common shares for extinguishment of convertible debt	—	—	—	—	6,825,391	6,825	11,778,162	—	11,784,987
Issuance of common shares for extinguishment of dividends payable	—	—	—	—	954,696	955	4,772,525	—	4,773,480
Issuance of common shares from IPO, net of costs	—	—	—	—	2,172,591	2,173	9,871,494	—	9,873,667
Issuance of common shares for accelerated vesting	—	—	—	—	127,500	127	(127)	—	—
Accrued preferred dividends	—	—	—	—	—	—	—	(160,219)	(160,219)
Net loss	—	—	—	—	—	—	—	(3,208,345)	(3,208,345)
Debt forgiveness	—	—	—	—	—	—	434,065	—	434,065
Balance, March 31, 2019	—	—	—	—	14,613,000	$ 14,613	$ 49,896,966	$ (45,499,839)	$ 4,411,740

See accompanying notes to the unaudited condensed financial statements

SOLITON, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	For the Three Months Ended March 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,270,503)	$ (3,208,345)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	70,767	29,703
Stock-based compensation	711,486	512,045
Amortization of debt discount	—	664,953
Deferred rent	(2,387)	(1,006)
Changes in operating assets - (increase)/decrease:		
Prepaid expenses and other current assets	(816,859)	(220,349)
Changes in operating liabilities - increase/(decrease):		
Accounts payable	(349,541)	(1,161,769)
Accrued liabilities	(664,763)	(68,853)
Non-convertible accrued interest - non-related and related party	—	10,617
Convertible accrued interest - related party	—	145,667
NET CASH USED IN OPERATING ACTIVITIES:	(4,321,800)	(3,297,337)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Payments for the purchase of property and equipment and trademark registration	(10,099)	(784,568)
NET CASH USED IN INVESTING ACTIVITIES:	(10,099)	(784,568)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of non-convertible notes payable and accrued interest - related party and non-related party	—	(1,005,038)
Proceeds from the issuance of non-convertible notes payable - non-related party	—	300,000
Proceeds from initial public offering	—	9,714,198
NET CASH PROVIDED BY FINANCING ACTIVITIES:	—	9,009,160
Net (decrease) increase in cash	(4,331,899)	4,927,255
Cash, beginning of period	12,076,425	133,435
Cash, end of period	$ 7,744,526	$ 5,060,690
Supplemental cash flow disclosures:		
Cash paid for interest	$ —	$ 20,038
Non-cash financing activities:		
Accrued preferred dividends	$ —	$ 160,219
Accrued direct issuance costs - offering	$ —	$ (276,560)
Capital contributions - debt forgiveness	$ —	$ 434,065
Issuance of common stock for extinguishment of convertible note payable and accrued interest - related party and non-related party	$ —	$ 11,784,987
Issuance of common stock for extinguishment of dividends payable	$ —	$ 4,776,015
Debt discount on convertible notes and notes payable - issuance of warrants	$ —	$ 145,974

See accompanying notes to the unaudited condensed financial statements

SOLITON, INC.

NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1 - Description of the Business and Summary of Significant Accounting Policies

Description of the Business

Soliton, Inc. (“Soliton” or the “Company”) was organized under the laws of the State of Delaware on March 27, 2012. The Company operates in one segment as a medical device company organized to develop and commercialize products utilizing a proprietary Rapid Acoustic Pulse ("RAP") technology platform. The Company is a pre-revenue stage company with its first product being developed for the removal of tattoos. In addition, the Company has recently completed a proof-of-concept clinical trial for the reduction of cellulite and has initiated a four-site pivotal trial for the reduction of cellulite. The Company is based in Houston, Texas. Upon completion of the development of its products and regulatory clearances to market such products, the Company anticipates revenue will be driven by the sale of its RAP console and disposable cartridges to dermatologists, plastic surgeons and other physician offices, as well as medi-spas under the supervision of a doctor.

Initial Public Offering

On February 19, 2019, the Company consummated its initial public offering (“IPO”). In the IPO, the Company sold a total of 2,172,591 shares of common stock at a purchase price of $5.00 per share for gross proceeds of $10,862,955 and net proceeds of $9,714,198. In connection with the closing of the IPO, convertible notes (and related accrued interest) of $11,784,987 were initially converted into 6,825,391 shares of common stock, accrued dividends of $4,773,480 were converted into 954,696 shares of common stock, and preferred stock, both Series A and Series B, was converted into 2,534,766 shares of common stock. In addition, 127,500 shares of unvested restricted grants were immediately vested upon the completion of the IPO. Total shares of common stock outstanding at the closing of the IPO amounted to 14,613,000. Upon the closing of the IPO, certain notes were to be automatically converted, according to their terms, into common stock, to the extent and provided that certain holders of these notes are not permitted to convert such notes to the extent that the holders or any of its affiliates would beneficially own in excess of 4.99% of the Company’s common stock after such conversion. Due to this 4.99% limitation, principal representing $47,781 of these notes remained outstanding and were converted into 273,034 shares of its common stock in August and September 2019 when the conversion did not result in the holders and any of its affiliates owning more than 4.99% of the Company's outstanding common shares.

Private Investment in Public Equity Offerings

On June 16, 2019, the Company entered into a private offering with certain institutional and accredited investors for the sale by the Company of 675,000 units (each a “June Unit”) of common stock issued at $14.00 per June Unit for total gross proceeds of $9,450,000. Each June Unit consisted of (i) one share of the Company’s common stock, and (ii) a warrant to purchase 0.7 shares (a total of 472,500) of common stock (each a “June Warrant”) (collectively, "June PIPE"). The June Warrants included in the June Units are exercisable at a price of $16.00 per share commencing on the date of issuance and will expire on August 23, 2024. On July 1, 2019, the Company filed a Registration Statement on Form S-1 to register for resale the common stock underlying the June Units. Net proceeds from the closing of the sale of the June Units on June 19, 2019 was $8,643,302 after deducting placement agent fees and estimated offering expenses.

On October 10, 2019, the Company entered into a private offering with certain institutional and accredited investors for the sale by the Company of 485,250 units (each an “October Unit”) of common stock issued at $12.88 per October Unit for total gross proceeds of $6,250,020. Each October Unit consisted of (i) one share of the Company’s common stock and (ii) a warrant to purchase 1.1 shares (a total of 533,775) of common stock (each an “October Warrant”) (collectively, "October PIPE"). The October Warrants included in the October Units are exercisable at a price of $12.88 per share commencing on the date of issuance and will expire on October 10, 2024. On November 8, 2019, the Company filed a Registration Statement on Form S-1 to register for resale the common stock underlying the October Units sold with the Company's October 2019 private offering. Net proceeds from the closing of the sale of the October Units on October 11, 2019 was $5,738,111 after deducting placement agent fees and estimated offering expenses.

Going Concern

The Company is an early stage and emerging growth company and has not generated any revenues to date. As such, the Company is subject to all of the risks associated with early stage and emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities.

For the three months ended March 31, 2020 and 2019, the Company incurred net losses of $3,270,503 and $3,208,345, respectively, had net cash flows used in operating activities of $4,321,800 and $3,297,337, respectively. At March 31, 2020, the Company had an accumulated deficit of $59,313,874, working capital of $6,807,893 and cash, cash equivalents and restricted cash of $7,744,526. The Company does not expect to experience positive cash flows from operating activities in the near future, if at all. The Company anticipates incurring operating losses for the next several years as it completes the development of its products and seeks requested regulatory clearances to market such products. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The accompanying financial statements have been prepared on a going concern basis and do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The Company's cash, cash equivalents and restricted cash on hand of $7,744,526 as of March 31, 2020 is sufficient to fund the Company's operations into December 2020 but not beyond. The Company also believes it will need to raise additional capital in order to continue to execute its business plan, including obtaining additional regulatory clearance for its products currently under development and commercializing and generating revenues from products under development. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company. A failure to raise sufficient capital will adversely impact the Company's ability to meet its financial obligations as they become due and payable and to achieve its intended business objectives. If the Company is unable to raise sufficient additional funds, it will have to scale back its operations.

Basis of Presentation

The accompanying condensed interim financial statements are unaudited. These unaudited interim financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and notes required by accounting principles generally accepted in the United States of America ("GAAP") for complete financial statements. These unaudited condensed interim financial statements should be read in conjunction with the audited financial statements and accompanying notes as found in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 2, 2020. In the opinion of management, the unaudited condensed interim financial statements reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position, results of operations and cash flows for the interim periods presented. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2019 balance sheet included herein was derived from the audited financial statements, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Segments

The Company operates in one reportable segment based on management's view of its business for purposes of evaluating performance and making operating decisions.

Use of Estimates in Financial Statement Presentation

The preparation of these financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company's significant estimates and assumptions include work performed but not yet billed by contract manufacturers, engineers and research organizations, the valuation of equity related instruments, depreciable lives of long-lived assets (including property and equipment and intangible assets), and the valuation allowance related to deferred taxes. Although the Company believes that its estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Some of these judgments can be subjective and complex, and, consequently, actual results could differ from those estimates.

The coronavirus disease ("COVID-19") pandemic has negatively impacted, and may continue to negatively impact, the macroeconomic environment in the United States and globally, including our business, financial condition and results of operations. Due to the evolving and uncertain nature of COVID-19, it is reasonably possible that it could materially impact our estimates, particularly those that require consideration of forecasted financial information, in the near to medium term. These estimates relate to certain accounts including, but not limited to, the valuation allowance related to deferred taxes, intangible assets, and other long-lived assets. The magnitude of the impact will depend on numerous evolving factors that we may not be able to accurately predict, including the duration and extent of the pandemic, the impact of federal, state, local and foreign governmental actions, consumer behavior in response to the pandemic and such governmental actions, and the economic and operating conditions that we may face in the aftermath of COVID-19.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid accounts with original maturities of three months or less to be cash equivalents or restricted cash. The Company participates in an insured cash sweep program through its bank that sweeps cash balances exceeding the FDIC insured limit of $250,000 into multiple accounts. Periodically in the ordinary course of business, the Company may carry cash balances at financial institutions in excess of the insured limits of $250,000.

Restricted cash consists of amounts held in deposit with the Company's bank to collateralize a letter of credit which supports the Company's obligations to pay or perform according to the requirements of an underlying agreement with a certain vendor. Such letter of credit has an initial term of one year, renews automatically and can only be modified or canceled with the approval of the beneficiary. As of March 31, 2020, the letter of credit was not used.

Property and Equipment

Property and equipment are stated at historical cost and depreciated on a straight-line basis over the estimated useful lives, generallythree to five years. Leasehold improvements are depreciated over the shorter of the remaining lease term or useful lives of the assets. Upon disposition of the assets, the costs and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Repairs and maintenance costs are included as expense in the accompanying condensed statements of operations.

Intangible Assets

Intangible assets include trademarks. At March 31, 2020 and December 31, 2019, the Company had capitalized trademark costs of $98,289 and $97,556, respectively. Trademarks have indefinite useful lives as the Company can protect and renew them indefinitely. The Company evaluates the recoverability of intangible assets periodically and takes into account events or circumstances that warrant revised estimates of useful lives or that indicate that impairment exists. No material impairments of intangible assets have been identified during any of the periods presented.

Long-Lived Assets

The Company evaluates its long-lived assets, including equipment and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows expected to result from the use of the asset and its eventual disposition. If the asset is considered impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired assets.

Deferred Rent

Deferred rent is recorded and amortized to the extent the total minimum rental payments allocated to the current period on a straight-line basis differ from the cash payments required.

Fair Value Measurements

Fair value is defined as the price which would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. A three-tier fair value hierarchy which prioritizes the inputs used in the valuation methodologies, as follows:

Level 1 Inputs - Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.

Level 3 Inputs - Unobservable inputs for determining the fair values of assets or liabilities that reflect an entity's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities.

At March 31, 2020 and December 31, 2019, the carrying amounts of the Company's financial instruments, including cash and cash equivalents, restricted cash and accounts payable, approximate their respective fair value due to the short-term nature of these instruments.

At March 31, 2020 and December 31, 2019, the Company does not have any assets or liabilities required to be measured at fair value on a recurring basis.

Deferred Direct IPO Issuance Costs – Offering

At December 31, 2018, the Company had capitalized offering costs of $276,560, consisting of legal, accounting and other fees and costs related to the IPO, which were reclassified to additional paid-in capital as a reduction of the proceeds upon the closing of the IPO in February 2019.

Warrants to Purchase Common Stock

The Company issued warrants to purchase shares of common stock related to (i) bridge notes issued prior to its IPO, (ii) private investment in public equity ("PIPE") offerings, and (iii) as part of underwriter compensation in 2019 and 2018. The Company accounted for such warrants in accordance with Accounting Standards Codification (ASC) Topic 480-10, *Distinguishing Liabilities from Equity*, which identifies three categories of freestanding financial instruments that are required to be accounted for as a liability. Based on this guidance, the Company determined, for each issuance, that its warrants did not need to be accounted for as a liability. Accordingly, the warrants were classified as equity and are not subject to remeasurement at each balance sheet date. In addition, the Company accounts for issuance costs of warrants issued with debt instruments in accordance with ASC 470-20, *Debt with Conversion and Other Options*, which states proceeds from the sale of a debt instrument with stock purchase warrants (detachable call options) are allocated to elements based on the relative fair values of the debt instrument without the warrants and of the warrants themselves at time of issuance. The portion of the proceeds so allocated to the warrants are accounted for as additional paid-in capital. The remainder of the proceeds are allocated to the debt instrument, which may result in a discount or premium.

On July 1, 2019, the Company filed a Registration Statement on Form S-1 to register for resale the common stock underlying the June Units sold with the Company's June 2019 private offering. In addition, on November 8, 2019, the Company filed a Registration Statement on Form S-1 to register for resale the common stock underlying the October Units sold with the Company's October 2019 private offering. Related registration rights agreements are accounted for in accordance with Topic ASC Topic 450-20, *Loss Contingencies*, which requires measurement of the contingent liability when an entity would be required to deliver shares under a registration payment arrangement, the transfer of consideration is probable and the number of shares to be delivered can be reasonably estimated. Accordingly, there is no liability under the payment arrangement requiring disclosure or recognition.

The fair value of warrants is estimated using the Black-Scholes option pricing model, based on the market value of the underlying common stock at the measurement dates, the contractual terms of the warrants, risk-free interest rates and expected volatility of the price of the underlying common stock. There are no expected dividends.

Research and Development Expenses

Research and development expenses are recognized as incurred and include the costs related to the Company's various contract research service providers, suppliers, engineering studies, supplies, outsourced testing and consulting, clinical costs, patent costs, stock-based compensation and salaries and related costs of employees working directly on research activities.

Stock-Based Compensation

Stock-based compensation expense includes the estimated fair value of equity awards vested or earned during the reporting period. The expense for equity awards vested during the reporting period is determined based upon the grant date fair value of the award and is recognized as expense over the applicable vesting period of the stock award using either the straight-line method or the accelerated method, depending on the vesting structure, and is included in research and development and general and administrative expenses. Expense for non-employee awards is recorded as if the Company had paid cash for the goods or services. The Company accounts for forfeitures as they occur by reversing compensation cost when the award is forfeited.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of reported assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to

reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Tax rate changes are reflected in income during the period such changes are enacted. All of the Company's tax years remain subject to examination by the tax authorities.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of deferred assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company has recorded a full valuation allowance against its net total deferred tax assets as of March 31, 2020 and December 31, 2019 because management determined that it is not more-likely-than not that those assets will be realized. Accordingly, there was no income tax benefit for all periods presented.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's financial statement as of March 31, 2020. The Company does not expect any significant changes in the unrecognized tax benefits within twelve months of the reporting date.

The Company classifies interest expense and any related penalties related to income tax uncertainties as a component of income tax expenseNo interest or penalties have been recognized for the three months ended March 31, 2020 and 2019.

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. The Company's unvested stock awards that contain non-forfeitable rights to dividends or dividend equivalents, whether paid or unpaid, are considered participating securities and are contemplated in the computations of basic and diluted earnings or loss per share. These securities do not participate in losses and accordingly no such allocation has been made in the periods presented. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive.

As of March 31, 2020, potentially dilutive securities included options to purchase3,271,050 common shares, warrants to purchase 1,359,608 common shares and unvested restricted stock of 145,838 shares.

As of March 31, 2019, potentially dilutive securities included options to purchase2,636,750 common shares and warrants to purchase1,228,431 common shares.

JOBS Act Accounting Election

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). The JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-EGCs but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised, and it has different application dates for public or private companies, the Company, as an EGC, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company’s financial statements with another public company which is neither an EGC nor an EGC which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Subsequent Events

The Company’s management reviewed all material events through the date that the financial statements were issued for subsequent event disclosure consideration. See Note 7 and elsewhere in the notes to the financial statements for additional information.

Recent Accounting Standards

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02,*“Leases (Topic 842)”*, which establishes a right-of-use (“ROU”) model requiring a lessee to recognize a ROU asset and a lease liability for all leases with terms greater-than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. This guidance is currently effective, for public EGC companies like the Company,

for fiscal years beginning after December 15, 2020 and may include interim periods within those fiscal years. The modified retrospective transition approach applies to leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company has the option to instead apply the provisions at the effective date without adjusting the comparative periods presented. The Company is currently evaluating the impact of this guidance on its financial position, results of operations, and cash flows.

The Company does not believe that any other recently issued effective standards, or standards issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

Reclassifications

In certain instances, amounts reported in prior years' consolidated financial statements have been reclassified to conform to the current financial statement presentation. Such reclassifications had an effect on previously reported cash flows between operating and investing activities.

Note 2 - Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	March 31, 2020	December 31, 2019
Prepaid insurance	$ 493,526	$ 93,950
Other prepaids and receivables	419,643	2,360
Total prepaid expenses and other current assets	$ 913,169	$ 96,310

As of March 31, 2020, other prepaids and receivables largely included approximately $350,000 for payments made to vendors for work that has not yet been completed and approximately $42,000 for payments made as a result of listing requirements for public companies.

Note 3 - Property and Equipment

Property and equipment consisted of the following:

	March 31, 2020	December 31, 2019
Computer equipment and software	$ 133,264	$ 126,643
Research and development equipment	247,226	244,480
Lab equipment	780,000	780,000
Leasehold improvements	271,124	271,124
Furniture	19,893	19,893
Subtotal	1,451,507	1,442,140
Less: accumulated depreciation	(665,509)	(594,741)
Total property and equipment, net	$ 785,998	$ 847,399

As of March 31, 2020 and December 31, 2019, the Company had $650,000 and $689,000, respectively, of lab equipment, net, in the field at clinical trial sites and held by a vendor for future clinical use. Depreciation of this equipment started when it was placed in service in June 2019.

Depreciation expense for the three months ended March 31, 2020 and 2019 was $70,767 and $29,703, respectively.

Note 4 - Convertible Notes Payable

On February 19, 2019, the Company consummated its IPO. In connection with the closing of the IPO, convertible notes (and related accrued interest) of $1,784,987 were converted into 6,825,391 shares of common stock. Upon the closing of the IPO, certain notes were to be automatically converted, according to their terms, into common stock, to the extent and provided

that certain holders of these notes are not permitted to convert such notes to the extent that the holders or any of its affiliates would beneficially own in excess of 4.99% of the Company's common stock after such conversion. Due to this 4.99% limitation, principal representing $47,781 of these notes remained outstanding and were converted into 273,034 shares of its common stock in August and September 2019 when the conversion did not result in the holders and any of its affiliates owning more than 4.99% of the Company's outstanding common shares. All remaining debt instruments were settled at the closing of the IPO.

Note 5 - Commitments and Contingencies

On April 5, 2012, the Company entered into a Patent and Technology License Agreement with The University of Texas M.D. Anderson Cancer Center ("MD Anderson"). Pursuant to the agreement, the Company obtained a royalty-bearing, worldwide, exclusive license to intellectual property including patent rights related to the patents and technology the Company uses. Under the agreement, the Company paid a nonrefundable license documentation fee in the high-five digits 30 days after the effective date of the agreement. Additionally, the Company agreed to pay a nonrefundable annual maintenance fee starting on the third anniversary of the effective date of the agreement, which escalates each anniversary and is currently in the mid-five digits. Additionally, the Company agreed to a running royalty percentage of net sales in the mid-single digits. The Company also agreed to make certain milestone payments in the low to mid-six digits and sublicensing payments. The specific patents initially subject to the agreement expire between 2031 and 2032.

MD Anderson has the right to terminate the agreement upon advanced notice in the event of a default by the Company. The agreement will expire upon the expiration of the licensed intellectual property. The rights obtained by the Company pursuant to the agreement are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government. To the extent that is the case, the Company's license agreement with, and the intellectual property rights it has licensed from MD Anderson, are subject to such a funding agreement and any superior rights that the U.S. government may have with respect to the licensed intellectual property. Therefore, there is a risk that the intellectual property rights the Company has licensed from MD Anderson may be non-exclusive or void if a funding agreement related to the licensed technology between MD Anderson and the U.S. government does exist and depending on the terms of such an agreement. Notwithstanding the foregoing, the Company does not believe our RAP technology received any federal funding. All out-of-pocket expenses incurred by MD Anderson in filing, prosecuting and maintaining the licensed patents have been and shall continue to be assumed by the Company.

As the inventor of the intellectual property licensed from MD Anderson, Dr. Capelli, the Company's Chief Executive Officer, is entitled to 50% of the license income (which is determined after MD Anderson recoups any costs associated therewith) that the Company is required to pay to MD Anderson pursuant to the Company's license agreement with MD Anderson. In addition, Dr. Capelli is entitled to 50% of the proceeds (after the recoupment of any costs associated therewith) from the sale by MD Anderson of 175,000 shares issued to MD Anderson in connection with the license agreement.

Purchase Commitments

On November 20, 2019, the Company entered into a cooperative development addendum ("Addendum") to its engineering and development services master agreement with Emphysys, Inc. ("Emphysys"). The Addendum states that Emphysys will provide the Company with engineering and design services related to shockwave technology for use in dermatology and aesthetics fields for a three year period.

During the term of the Addendum, the Company agreed to certain minimum annual expenditures. If the Company fails to spend such minimum annual amounts or if the Company terminates the Addendum without cause, the Company will be required to pay Emphysys a termination fee ranging in the low to mid-six digits. In the event that all or substantially all of the stock or assets of either party are sold then, at the request of the other party, the Addendum may be terminated (without the requirement to pay a termination fee) and the obligation of Emphysys to provide future services to the Company shall terminate. Pursuant to the Addendum, with certain exceptions, Emphysys covenanted that it will not perform or agree to perform services with any company other than Soliton in the area of arc-discharge driven acoustical shockwave generation for medical dermatological or aesthetic dermatological indications during the term of the Addendum or any extension thereof, and for a period of six months after the termination of the Addendum.

As of March 31, 2020, the Company had purchase obligations of $3,376,166 to Emphysys. This commitment is for services used in the ordinary course of business and does not represent excess commitments or loss contracts. This commitment can be terminated with a penalty payment of no more than $500,000.

Year Ending December 31,	Amount
2020	$ 1,013,666
2021	1,575,000
2022	787,500
Total future minimum purchase commitments	$ 3,376,166

On March 6, 2020, the Company entered into a manufacturing service agreement (the "Agreement") with Sanmina Corporation ("Sanmina"). The Agreement states that Sanmina will provide the Company with certain manufactured products for a one year period, with pricing adjusted for material variations of market prices for components, parts and raw material, including variations resulting from allocations, shortages or tariffs. In addition, pricing will be based on the forecasted volumes provided by the Company and the projected inventory turns as agreed by both parties.

Either party may terminate the Agreement or an order under the Agreement for default, if the other party materially breaches the Agreement; provided, however, no termination shall occur until thirty days after the defaulting party is notified in writing of the material breach and has failed to cure or give adequate assurances of performance within the thirty day period after notice of material breach. In addition, the Company may terminate the Agreement for any reason upon thirty days' prior written notice and may terminate any order under the Agreement for any reason upon 120 days' (before scheduled shipment) prior written notice. Sanmina may terminate the Agreement for any reason upon ninety days' notice. In the event the Agreement or an order under the Agreement is terminated for any reason other than a breach by Sanmina, the Company is required to pay Sanmina, termination charges equal to (i) the contract price for all finished product existing at the time of termination; (ii) Sanmina's cost (including labor, components and applicable mark-ups per the pricing model) for all work in process; and (iii) the cost of components ordered by Sanmina pursuant to the Agreement.

Lease Commitments

The Company leases space for its corporate office, which provides for a63 month term beginning on February 1, 2016, for rent payments of $7,867 per month. Total rent expense under this office space lease arrangement for each of the three months ended March 31, 2020 and 2019 was $23,602 and $24,157, respectively.

Future minimum lease payments as of March 31, 2020 were as follows:

Year Ending December 31,	Amount
2020	$ 80,164
2021	35,751
Total future minimum lease payments	$ 115,915

Letters of Credit

The Company has an irrevocable letter of credit which supports its obligations to pay or perform according to the requirements of an underlying agreement with a certain vendor. Such letter of credit has an initial term of one year, renews automatically for an additional year and can only be modified or canceled with the approval of the beneficiary. As of March 31, 2020, the letter of credit was not used.

Legal Proceedings

In the normal course of business, from time-to-time, the Company may be subject to claims in legal proceedings. However, the Company does not believe it is currently a party to any pending legal actions. Notwithstanding, legal proceedings are subject-to inherent uncertainties, and an unfavorable outcome could include monetary damages, and in such event, could result in a material adverse impact on the Company's business, financial position, results of operations or cash flows.

Employment Agreements

The Company has agreements with certain employees to provide certain benefits in the event of termination where the base salary and certain other benefits would amount to $1,719,840 using the rate of compensation in effect at March 31, 2020.

Note 6 - Stockholders' (Deficit) Equity

Preferred Stock

On February 19, 2019, all outstanding shares of Series A and Series B preferred stock and accrued dividends on these shares were converted into 2,534,766 and 954,696 shares of common stock upon the closing of the Company's IPO. The Company amended its articles of incorporation on February 19, 2019 to no longer have preferred shares authorized under the amended certificate of incorporation.

Adoption of 2012 Long Term Incentive Plan

In November 2012, the Company's Board and stockholders adopted the 2012 Long Term Incentive Plan (the "2012 Stock Plan"). The 2012 Stock Plan is designed to enable the Company to offer employees, officers, directors and consultants, as defined, an opportunity to acquire a proprietary interest in the Company. The types of awards that may be granted under the 2012 Stock Plan include stock options, stock appreciation rights, restricted stock, and other stock-based awards subject to limitations under applicable law. All awards are subject to approval by the Company's Board. The 2012 Stock Plan reserves shares of common stock for issuance in accordance with the 2012 Stock Plan's terms. Total number of shares reserved and available for issuance under the plan is 789,745 shares. As of March 31, 2020, 14,745 shares remained under the 2012 Stock Plan. The Company no longer utilizes the 2012 Stock Plan and instead utilizes the 2018 Stock Plan.

Adoption of 2018 Stock Plan

In June 2018, the Company's Board and stockholders adopted the 2018 Stock Plan. The 2018 Stock Plan is designed to enable the Company to offer employees, officers, directors and consultants, as defined, an opportunity to acquire a proprietary interest in the Company. The types of awards that may be granted under the 2018 Stock Plan include stock options, stock appreciation rights, restricted stock, and other stock-based awards subject to limitations under applicable law. All awards are subject to approval by the Company's Board. The 2018 Stock Plan reserves shares of common stock for issuance in accordance with the 2018 Stock Plan's terms. Total number of shares reserved and available for issuance under the plan is 3,400,000 shares. As of March 31, 2020, 143,950 shares remained available for grant under the 2018 Stock Plan.

Restricted Stock

Restricted stock activity for the three months ended March 31, 2020 is summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding, December 31, 2019	158,336	$ 11.54
Vested	(12,498)	11.54
Outstanding, March 31, 2020	145,838	$ 11.54

On May 8, 2019, the Company granted and issued 200,000 shares of restricted common stock to three consultants in connection with the provision of services pursuant to agreements entered into in April 2019. The consultants were each accredited investors. 25,000 shares vested within four months of the approval date of the agreement. The remaining 175,000 shares vest over 42 months, beginning on September 19, 2019. As of March 31, 2020, 54,162 shares have vested and 145,838 remain unvested.

During the three months ended March 31, 2020 and 2019, the Company recorded $126,219 and $264,453, respectively, in stock-based compensation for the restricted shares previously issued.

As of March 31, 2020, there was $1,556,698 of unrecognized compensation expense related to restricted shares.

Stock Options

The following table summarizes stock option activities for the three months ended March 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2019	2,883,550	$ 2.70	8.62	$ 23,861,981
Granted	387,500	11.74	—	—
Outstanding, March 31, 2020	3,271,050	$ 3.77	8.53	$ 15,391,278
Exercisable, March 31, 2020	968,950	$ 1.74	8.45	$ 6,528,096

During the three months ended March 31, 2020, the Company granted certain individuals options to purchase387,500 shares of common stock with an average exercise price of $11.74 per share, with contractual terms ranging from five to ten years, and vesting periods ranging from 8.33% monthly over one year to25.00% per year over four years. The options have an aggregate grant date fair value of $3,247,052 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rates ranging from 1.42% to 1.56% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected lives ranging from 5.75 to 6.25 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility ranging from83.1% to 83.4% based on the historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair value of the Company's stock ranging from $11.71 to $13.50 per share.

All options issued and outstanding are being amortized over their respective vesting periods. During the three months ended March 31, 2020 and 2019, the Company recorded option expense of $585,267 and $247,592, respectively. The unrecognized compensation expense for options at March 31, 2020 was $6,146,925.

Warrants

During the year ended December 31, 2018, the Company issued warrants to purchase776,350 shares of common stock at an exercise price of $1.75. The warrants expire five years from the date of issuance. The warrants were issued to placement agents and investors in connection with certain notes.

In January and February 2019, the Company issued warrants to purchase300,000 shares of common stock at an exercise price of $1.75 on various dates. The warrants were issued to investors in connection with certain notes.

On February 19, 2019, the Company issued warrants to the underwriters of the Company's IPO to purchase152,081 shares of common stock at an exercise price of $6.00. The warrants expire five years from the date of issuance.

The aggregate grant date fair value of these 1,228,431 warrants was $1,636,232, which was determined utilizing the Black-Scholes option pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rates in the range of 2.5% to 2.8% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected terms of five years based on the terms of the warrants, (3) expected volatility of84% to 85% based on the historical volatility of comparable companies' stock, (4) no expected dividends, and (5) fair value of the Company's stock at $1.67 per share for warrants issued prior to the IPO, a value determined by the Company's Board of Directors after reviewing and considering, among other factors, a valuation report issued by an independent appraisal firm, or the fair value of the Company's stock at the closing of its' IPO on February 19, 2019 of $4.87 for warrants on that day.

The fair value amount was included in discounts on convertible notes payable and was amortized over the life of the convertible notes payable. As a result of the Company’s IPO closing on February 19, 2019, $664,953 of unamortized discount on convertible notes payable was accelerated and recorded as expense.

PIPE Offerings

On June 16, 2019, the Company entered into a private offering with certain institutional and accredited investors for the sale by the Company of 675,000 units (each a “June Unit”) of common stock issued at $14.00 per June Unit for total gross proceeds of $9,450,000. Each June Unit consisted of (i) one share of the Company’s common stock, and (ii) a warrant to purchase 0.7 shares (a total of 472,500) of common stock (each a “June Warrant”) (collectively, "June PIPE"). The June Warrants included in the June Units are exercisable at a price of $16.00 per share commencing on the date of issuance and will expire on August 23, 2024. On July 1, 2019, the Company filed a Registration Statement on Form S-1 to register for resale the common stock underlying the June Units sold with the Company's June 2019 private offering. Net proceeds from the closing of the sale of the June Units on June 19, 2019 were $8,643,302 after deducting the placement agent fees and offering expenses.

The grant date fair value of these 472,500 June Warrants was $4,420,503, which was determined utilizing the Black-Scholes option pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rate of 1.85% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected term of five years based on the term of the warrants, (3) expected volatility of 85% based on the historical volatility of comparable companies' stock, (4) no expected dividends, and (5) fair value of the Company's stock at $14.30 per share.

On October 10, 2019, the Company entered into a private offering with certain institutional and accredited investors for the sale by the Company of 485,250 units (each an “October Unit”) of common stock issued at $12.88 per October Unit for total gross proceeds of $6,250,020. Each October Unit consisted of (i) one share of the Company’s common stock and (ii) a warrant to purchase 1.1 shares (a total of 533,775) of common stock (each an “October Warrant”) (collectively, "October PIPE"). The October Warrants included in the October Units are exercisable at a price of $12.88 per share commencing on the date of issuance and will expire on October 10, 2024. On November 8, 2019, the Company filed a Registration Statement on Form S-1 to register for resale the common stock underlying the October Units sold with the Company's October 2019 private offering. Net proceeds from the closing of the sale of the October Units on October 11, 2019 were $5,738,111 after deducting the placement agent fees and offering expenses.

The grant date fair value of these 533,775 October Warrants was $4,537,648, which was determined utilizing the Black-Scholes option pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rate of 1.59% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected term of five years based on the term of the warrants, (3) expected volatility of 82.92% based on the historical volatility of comparable companies' stock, (4) no expected dividends, and (5) fair value of the Company's stock at $12.88 per share.

The fair value amount of these PIPE transaction warrants were included in additional paid-in-capital as deal costs.

The following table summarizes warrant activity for the three months ended March 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2019	1,374,608	$ 10.97	4.43	$ 13,591
Granted	—	—	—	—
Exercised	(11,394)	1.75	—	76,682
Forfeited (cashless exercise)	(3,606)	1.75	—	—
Outstanding, March 31, 2020	1,359,608	$ 11.07	4.19	$ —
Exercisable, March 31, 2020	1,359,608	$ 11.07	4.19	$ —

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes appearing elsewhere in this Form 10-Q. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 2, 2020 (the "2019 Annual Report on Form 10-K"), under "Risk Factors", available on the Security and Exchange Commission's ("SEC") EDGAR website at www.sec.gov, for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Form 10-Q.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other sections of this Form 10-Q. In some cases, you can identify these statements by forward-looking words such as "may," "might," "should," "would," "could," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or "continue," and the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to known and unknown risks, uncertainties and assumptions about us, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the numerous risks and uncertainties described under "Risk Factors" as discussed in our 2019 Annual Report on Form 10-K and in other filings made by us from time to time with the SEC.

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this Form 10-Q may describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this Form 10-Q to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

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

- our ability to obtain additional funding to commercialize our Rapid Acoustic Pulse ("RAP") for tattoo removal, develop the RAP device for other indications and develop our dermatological technologies;
- the need to obtain regulatory approval for when we modify Generation 2 device to become our Generation 3 device before our nationwide launch, and the need to obtain regulatory approval for other indications;
- the success of our future clinical trials;
- compliance with obligations under our intellectual property license with The University of Texas M.D. Anderson Cancer Center ("MD Anderson");
- market acceptance of the RAP device;
- competition from existing products or new products that may emerge;
- potential product liability claims;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;

- our ability and third parties' abilities to protect intellectual property rights;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- risks associated with our identification of material weaknesses in our control over financial reporting;
- natural disasters affecting us, our primary manufacturer or our suppliers;
- our ability to establish relationships with health care professionals and organizations;
- market and economic uncertainty caused by the COVID-19 outbreak;
- general economic uncertainty that adversely effects spending on cosmetic procedures;
- volatility in the market price of our stock; and
- potential dilution to current stockholders from the issuance of equity awards.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this Form 10-Q in the case of forward-looking statements contained in this Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward looking-statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Overview

We are a medical technology company focused on developing and commercializing products utilizing our proprietary designed acoustic shockwave technology platform referred to as Rapid Acoustic Pulse ("RAP"). We are a pre-revenue stage company with our first product preparing for launch for the removal of tattoos. We received clearance for our initial device from the Food and Drug Administration ("FDA") on May 24, 2019 allowing our device to be used as an accessory to a 1064 Q-switch laser for tattoo removal in patients with Fitzpatrick Scale I-III skintones. Our product will need to receive clearance from the FDA, in order to be marketed for other indications in the United States. We also intend to secure regulatory approval in international markets and are currently developing a regulatory strategy for these markets.

Our business model anticipates generating revenue from the sale of our RAP console to dermatologists, plastic surgeons, and other physician offices, as well as medi-spas under the supervision of a doctor. Our model contemplates recurring revenues generated by the sale of disposable cartridges that are utilized with each patient visit and treatment. We believe additional revenues will result from maintenance services to our customers. Our system comprises a console with a hand piece and our consumable treatment cartridges, which are designed to allow a physician to perform a single office visit involving multiple laser passes on an average-sized tattoo or, if our cellulite reduction indication is approved in the future, a single stand-alone treatment for cellulite reduction. In simple terms, we expect this to translate into approximately one treatment cartridge per patient, per visit for tattoo and two cartridges per patient, per visit for cellulite, if approved.

Our ongoing research and development activities are primarily focused on finalizing the commercial device and cartridge design for tattoo removal, obtaining FDA clearance for our system for the treatment of cellulite, and then developing our system and treatment head for additional indications. In addition to these development activities, we are exploring additional uses of RAP technology for the dermatology, plastic surgery, and aesthetic markets, as well as new methods for improving the safety and efficacy of laser-based devices. We have completed proof-of-concept clinical trials for the reduction of cellulite and the treatment of fibrotic scars. We also concluded a pivotal study for the reduction of cellulite and expect to submit this data to the FDA for consideration in a 510(k) filing during the second quarter of 2020.

The medical technology and aesthetic product markets are highly competitive and dynamic and are characterized by rapid and substantial technological development and product innovations. We will compete with many other technologies for consumer demand. Further, the aesthetic industry in which we will operate is particularly vulnerable to economic trends. The

decision to undergo a procedure from our systems will be driven by consumer demand. Procedures performed using our systems will be elective procedures, the cost of which must be borne by the patient and are not reimbursable through government or private health insurance. In times of economic uncertainty or recession, individuals often reduce the amount of money that they spend on discretionary items, including aesthetic procedures. The general economic difficulties being experienced and the lack of availability of consumer credit for some of our customers' patients could adversely affect the markets in which we will operate.

Recent Developments

In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 ("COVID-19"), surfaced in Wuhan, China. In light of the widespread impact of COVID-19, our view of the ideal launch window for our RAP device has changed. Instead of launching our RAP device focused solely on tattoo removal in mid-2020, we are electing to delay that launch until the aesthetic and financial markets are demonstrating greater stability. In the meantime, we will remain highly focused on our regulatory pathway for cellulite reduction. We now believe our initial launch could be timed appropriately to incorporate both tattoo and cellulite indications, subject to FDA clearance of the latter.

As many dermatologist offices are currently closed, we are experiencing follow-up visit cancellations in our ongoing 26-week cellulite assessment and increased difficulty in executing the initiation of further clinical trials at sites around the country. While this will not impact the regulatory pathway for the initial cellulite indication, there is the expectation this will impact the timing of Soliton's planned additional hypertrophic scar proof-of-concept study and the longer-term 26-week follow-up visits in our cellulite pivotal study. Furthermore, it is possible this may extend the time required to file for additional, improved cellulite reduction claims with the FDA and for initial approvals of a hypertrophic scar indication that we may seek in the future.

We completed the 12-week follow up visit for our proof-of-concept trial targeting keloid and other hypertrophic scars and presented the results of this visit at the Maui Derm conference in January 2020. 3D scar assessment of the pre- and post-treatment photographs of 11 treated scars demonstrated an average reduction in volume of 29.6% ($p<0.01$) and an average reduction in height of 14.6% ($p<0.005$).

During the first quarter of 2020, we completed the follow-up visits for the patients enrolled in our cellulite pivotal study across four clinical sites. We treated 67 subjects and include results for 62 subjects in the results analysis due to exclusion of one subject and no show or incomplete follow-ups for another four subjects. Each patient received one treatment targeting dimples and ridges for approximately 20-30 minutes. There were no unexpected adverse events or significant adverse events. There was an average pain score of 2.42 on a 0-10 scale. As a measure of patient satisfaction, 91.9% of the subjects agreed or strongly agreed that their cellulite appeared improved. Representing a positive outcome, the primary endpoint of the study, a mean change in cellulite severity score of 1.0 or better, was exceeded with an actual mean change of 1.16. This change, represents a 31.4% reduction in the cellulite severity score for the 62 patients included in the study results.

Based on our revised spending plans, we estimate our cash resources, including cash, cash equivalents and restricted cash on hand of $7,744,526 at March 31, 2020 are sufficient to fund our operations into December of 2020 but not beyond. However, we cannot be certain that our business plan, including raising additional subsequent capital, obtaining regulatory clearance for its products currently under development, commercializing and generating revenues from products currently under development, and controlling expenses, will be achieved. A failure to raise sufficient capital will adversely impact our ability to meet our financial obligations as they become due and payable and to achieve our intended business objectives.

Results of Operations for the Three Months Ended March 31, 2020 Compared to the Three Months Ended March 31, 2019

Below is a summary of the results of operations:

	Three Months Ended March 31,			
	2020	2019	Change ($)	% Change
Operating expenses				
Research and development	$ 1,220,327	$ 445,402	$ 774,925	173.98 %
Sales and marketing	50,950	57,016	(6,066)	(10.64)%
Depreciation and amortization	70,767	29,703	41,064	138.25 %
General and administrative	1,932,690	1,854,684	78,006	4.21 %
Total operating expenses	$ 3,274,734	$ 2,386,805	$ 887,929	37.20 %

Research and development. Research and development ("R&D") expenses increased by $774,925 compared to the same period in 2019, due to increases in expenses for contract engineering of $496,672, clinical trials of $112,375, salaries and related costs of $60,678, stock-based compensation of $51,964 licenses and other expenses of $38,217 and travel and supplies of $15,019. The increase in R&D expense is largely related to our increased activity in cellulite trials.

Sales and marketing. Sales and marketing ("S&M") expenses decreased by $6,066 compared to the same period in 2019, primarily due to an increase in expenses related to social media development of $434 offset by a decrease in the related cost of meetings with our Scientific Advisory Board ("SAB") of $6,500. We include our SAB fees in S&M because they primarily advise on our product launch and marketing decisions related to dermatologists and prospective patients.

General and administrative. General and administrative ("G&A") expenses increased by $78,006 compared to the same period in 2019. This increase was primarily due to increases in salaries and related expenses of $20,449, comprised of a decrease in the payout of bonuses and the accrual for management incentives of $118,593 and increases in salaries and wages of $139,042. Additionally, we had increases in expenses for insurance of $88,987, accounting and other professional fess of $85,874, office related expenses of $14,468, information technology costs of $6,168 and legal of $4,230. These expenses were offset with decreases in investor relations of $157,618, dues and memberships of $82,031, board related fees of $44,580 and travel and related expenses of $5,418. Further contributing to the increase in G&A were the increases in non-cash expenses related to stock options and restricted stock of $147,477.

Liquidity and Capital Resources

Since our inception, we have financed our operations through public and private placements of common stock, convertible preferred stock and convertible and non-convertible bridge notes. On March 31, 2020, we had $7,544,526 of cash and cash equivalents and $200,000 in restricted cash representing a letter of credit benefiting our contract manufacturer.

On February 19, 2019, we consummated our IPO. In the IPO, we sold a total of 2,172,591 shares of common stock at a purchase price of $5.00 per share for gross proceeds of $10,862,955 and net proceeds of $9,714,198. In connection with the closing of the IPO, our convertible notes (and related accrued interest) of $11,784,987 were converted into 6,825,391 shares of our common stock, accrued dividends of $4,773,480 were converted into 954,696 shares of our common stock. We repaid non-convertible notes and accrued interest from our IPO proceeds in the amount of $1,005,038. Additionally, we utilized approximately $2,000,000 to pay outstanding liabilities with vendors.

On June 16, 2019, we entered into a private offering with certain institutional and accredited investors for the sale by us of 675,000 units (each a “June Unit”) of common stock issued at $14.00 per June Unit for total gross proceeds of $9,450,000. Each June Unit consisted of (i) one share of our common stock, and (ii) a warrant to purchase 0.7 shares (a total of 472,500) of common stock (each a “June Warrant”) (collectively, "June PIPE"). The June Warrants included in the June Units are exercisable at a price of $16.00 per share commencing on the date of issuance and will expire on August 23, 2024. On July 1, 2019, we filed a Registration Statement on Form S-1 to register for resale the common stock underlying the June Units sold with our June 2019 private offering. Net proceeds from the closing of the sale of the June Units on June 19, 2019 were $8,643,302 after deducting placement agent fees and offering expenses.

On October 10, 2019, we entered into a private offering with certain institutional and accredited investors for the sale by us of 485,250 units (each an “October Unit”) of common stock issued at $12.88 per October Unit for total gross proceeds of $6,250,020. Each October Unit consisted of (i) one share of our common stock and (ii) a warrant to purchase 1.1 shares (a total

of 533,775) of common stock (each an “October Warrant”) (collectively, "October PIPE"). The October Warrants included in the October Units are exercisable at a price of $12.88 per share commencing on the date of issuance and will expire on October 10, 2024. On November 8, 2019, we filed a Registration Statement on Form S-1 to register for resale the common stock underlying the October Units sold with our October 2019 private offering. Net proceeds from the closing of the sale of the October Units on October 11, 2019 were $5,738,111 after deducting placement agent fees and offering expenses.

We expect to continue to invest in our research and development efforts to support our current initiatives. We will not generate revenue until we have completed the commercialization of our RAP units and initiated sales of the units.

We estimate our current cash, cash equivalents and restricted cash resources of $7,744,526 at March 31, 2020 is sufficient to fund our operations into December of 2020 but not beyond. We also recognize we will need to raise additional capital in order to continue to execute our business plan, including obtaining regulatory clearance for our products currently under development and commercializing and generating revenues from products under development. There are no assurances that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us. A failure to raise sufficient capital, generate sufficient product revenues, control expenditures and regulatory matters, among other factors, will adversely impact our ability to meet our financial obligations as they become due and payable and to achieve our intended business objectives. If we are unable to raise sufficient additional funds, we will have to scale back our operations.

The COVID-19 global pandemic has resulted in travel restrictions and temporary shut-downs of non-essential businesses in many states in the United States. The Company is able to remain open but has required their employees to work from home. Due to the volatility of the stock markets resulting from travel restrictions and temporary business shut-downs, the Company faces challenges in raising substantial cash in the near-term. Due to many uncertainties, the Company is unable to estimate the pandemic’s financial impact or duration at this time.

Summary of Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2020 and 2019, respectively:

	Three Months Ended March 31,	
	2020	**2019**
Net cash used in operating activities	$ (4,321,800)	$ (3,297,337)
Net cash used in investing activities	(10,099)	(784,568)
Net cash provided by financing activities	—	9,009,160
Net (decrease) increase in cash	$ (4,331,899)	$ 4,927,255

Cash Flows for the three months ended March 31, 2020 and 2019

Operating activities. Net cash used in operating activities was $4,321,800 during the three months ended March 31, 2020 and consisted of a net loss of $3,270,503 and a net change in operating assets and liabilities of $1,831,163 offset by non-cash items of $779,866. The change in operating assets and liabilities included a use of cash for prepaid expenses and other assets of $816,859, accrued liabilities of $664,763 and accounts payable of $349,541. The increase in prepaid expenses was largely driven by new insurance policies, reporting software for public companies, and prepayments for work that had not yet been performed by an engineering contractor by March 31, 2020. The decrease in accounts payable was largely due to payments to several vendors and returning to consistent terms with vendors. The decrease in accrued liabilities was driven primarily by the settlement of accruals for several large vendors that were paid during the period. Non-cash items consisted of stock-based compensation of $711,486 and depreciation and amortization expense of $70,767 offset by deferred rent of $2,387.

Net cash used in operating activities was $3,297,337 during the three months ended March 31, 2019, and consisted of a net loss of $3,208,345 and a net change in operating assets and liabilities of $1,294,687 offset by non-cash items of $1,205,695. The change in operating assets and liabilities included a use of cash for prepaid expenses and other assets of $220,349, accounts payable of $1,161,769, accrued liabilities of $68,853 offset by accrued interest - non-related and related party of $156,284. The increase in accrued interest-related party is due to the issuance of the related party convertible notes and the calculation of interest thereon. Non-cash items consisted of accelerated amortization of debt discount of $664,953, stock-based compensation of $512,045, depreciation and amortization expense of $29,703 offset by deferred rent of $1,006.

Investing activities. Net cash used in investing activities for the three months ended March 31, 2020, was $10,099 compared to $784,568 for the same period in 2019. The decrease in cash used for equipment was largely due to $780,000 of lab equipment that was in the field at clinical trial sites and held by a vendor for future clinical use for the prior year period. For the three months ended March 31, 2020 and 2019, $9,366 and $3,430, respectively, was utilized towards the purchase of property and equipment as a result of the investment in our research equipment and office and research facilities. We invested $733 and $1,138 towards trademarks during the same periods in 2020 and 2019, respectively.

Financing activities. Net cash provided by financing activities during the three months ended March 31, 2020 was zero. For the three months ended March 31, 2019, due to our IPO, we received cash proceeds of $9,714,198, net of deal costs and other expenses, cash proceeds of $300,000 from the issuance of non-convertible notes payable to non-related parties. These amounts were offset by a use of cash for the payment of non-convertible notes and accrued interest to both related and non-related parties for $1,005,038.

Contractual Obligations and Commitments

On April 5, 2012, we entered into a Patent and Technology License Agreement with MD Anderson. Pursuant to the agreement, we obtained a royalty-bearing, worldwide, exclusive license to intellectual property including patent rights related to the patents and technology we use. Under the agreement, we agreed to pay a nonrefundable license documentation fee in the high-five digits 30 days after the effective date of the agreement. Additionally, we agreed to pay a nonrefundable annual maintenance fee starting on the third anniversary of the effective date of the agreement, which escalates each anniversary and is currently in the mid-five digits. Additionally, we agreed to a running royalty percentage of net sales in the mid-single digits. We also agreed to make certain milestone payments in the low to mid-six digits and sublicensing payments. The specific patents initially subject to the agreement expire between 2031 and 2032.

MD Anderson has the right to terminate the agreement upon advanced notice in the event of a default by Soliton. The agreement will expire upon the expiration of the licensed intellectual property. The rights obtained by us pursuant to the agreement are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government. To the extent that is the case, our license agreement with, and the intellectual property rights we have licensed from MD Anderson, are subject to such a funding agreement and any superior rights that the U.S. government may have with respect to the licensed intellectual property. Therefore, there is a risk that the intellectual property rights we have licensed from MD Anderson may be non-exclusive or void if a funding agreement related to the licensed technology between MD Anderson and the U.S. government does exist and depending on the terms of such an agreement. Notwithstanding the foregoing, we do not believe our RAP technology received any federal funding. All out-of-pocket expenses incurred by MD Anderson in filing, prosecuting and maintaining the licensed patents have been and shall continue to be assumed by us.

As the inventor of the intellectual property licensed from MD Anderson, Dr. Capelli, our Chief Executive Officer, is entitled to 50% of the license income (which is determined after MD Anderson recoups any costs associated therewith) that we are required to pay to MD Anderson pursuant to our license agreement with MD Anderson. In addition, Dr. Capelli is entitled to 50% of the proceeds (after the recoupment of any costs associated therewith) from the sale by MD Anderson of 175,000 shares issued to MD Anderson in connection with the license agreement.

On November 20, 2019, we entered into a cooperative development addendum ("Addendum") to our engineering and development services master agreement with Emphysys, Inc. ("Emphysys"). The Addendum states that Emphysys will provide us with engineering and design services related to shockwave technology for use in dermatology and aesthetics fields for a three-year period.

During the term of the Addendum, we agreed to certain minimum annual expenditures. If we fail to spend such minimum annual amounts or if we terminate the Addendum without cause, we will be required to pay Emphysys a termination fee ranging in the low to mid-six digits. In the event that all or substantially all of the stock or assets of either party are sold then, at the request of the other party, the Addendum may be terminated (without the requirement to pay a termination fee) and the obligation of Emphysys to provide future services to us shall terminate. Pursuant to the Addendum, with certain exceptions, Emphysys covenanted that it will not perform or agree to perform services with any company other than Soliton in the area of arc-discharge driven acoustical shockwave generation for medical dermatological or aesthetic dermatological indications during the term of the Addendum or any extension thereof, and for a period of six months after the termination of the Addendum.

On March 6, 2020, we entered into a manufacturing service agreement (the "Agreement") with Sanmina Corporation ("Sanmina"). The Agreement states that Sanmina will provide us with certain manufactured products for a one year period, with pricing adjusted for material variations of market prices for components, parts and raw material, including variations resulting

from allocations, shortages or tariffs. In addition, pricing will be based on the forecasted volumes provided by us and the projected inventory turns as agreed by both parties.

Either party may terminate the Agreement or an order under the Agreement for default, if the other party materially breaches the Agreement; provided, however, no termination shall occur until thirty days after the defaulting party is notified in writing of the material breach and has failed to cure or give adequate assurances of performance within the thirty day period after notice of material breach. In addition, we may terminate the Agreement for any reason upon thirty days' prior written notice and may terminate any order under the Agreement for any reason upon 120 days' (before scheduled shipment) prior written notice. Sanmina may terminate the Agreement for any reason upon ninety days' notice. In the event the Agreement or an order under the Agreement is terminated for any reason other than a breach by Sanmina, we are required to pay Sanmina, termination charges equal to (i) the contract price for all finished product existing at the time of termination; (ii) Sanmina's cost (including labor, components and applicable mark-ups per the pricing model) for all work in process; and (iii) the cost of components ordered by Sanmina pursuant to the Agreement.

Purchase Commitments

As of March 31, 2020, we had purchase obligations of $3,376,166 to a single engineering service provider. This commitment is for services used in the ordinary course of business and do not represent excess commitments or loss contracts. This commitment can be terminated with a penalty payment of no more than $500,000.

Year Ending December 31,	Amount
2020	$ 1,013,666
2021	1,575,000
2022	787,500
Total future minimum purchase commitments	$ 3,376,166

Lease Commitments

We lease space for our corporate office, which provides for a 63 month term beginning on February 1, 2016, for rent payments of $7,867 per month. Rent expense for non-cancellable operating leases with scheduled rent increases will be recognized on a straight-line basis over the lease term.

Future minimum lease payments under the operating leases as of March 31, 2020 were as follows:

Year Ending December 31,	Amount
2020	$ 80,164
2021	35,751
Total future minimum lease payments	$ 115,915

Employment Agreements

We have agreements with key employees to provide certain benefits in the event of termination where the base salary and certain other benefits would aggregate $1,719,840 using the rate of compensation in effect at March 31, 2020.

Unrecognized Tax Benefits

As of March 31, 2020, we have not recorded a provision for income taxes in our financial statements as we have been in a loss position since inception and we cannot be more certain than not that we will be able to recognize the income tax benefit from our net operating loss carry forwards in the future.

Off-balance Sheet Arrangements

As of March 31, 2020, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Significant Judgments and Estimates

The financial statements in this quarterly report have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the amounts reported in the financial statements, including the notes thereto. We consider critical accounting policies to be those that require more significant judgments and estimates in the preparation of our financial statements, including the following: research and development expenses, long lived assets; intangible assets valuations, accrued liabilities, income tax valuations, warrants, and stock-based compensation. Management relies on historical experience and other assumptions believed to be reasonable in making its judgments and estimates. Actual results could differ materially from those estimates.

Management believes its application of accounting policies, and the estimates inherently required therein, are reasonable. These accounting policies and estimates are periodically reevaluated, and adjustments are made when facts and circumstances dictate a change.

Our accounting policies are more fully described under the heading “Description of the Business and Summary of Significant Accounting Policies” in Note 1 to our Financial Statements included in this Form 10-Q.

We believe that the following accounting policies are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain.

Research and Development Costs

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conducting of pre-clinical studies, preparation for and conducting of clinical trials and contract engineering activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and we include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these third parties.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations, engineering firms and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Impairment of Long-Lived Assets

Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset’s carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its' carrying value.

Components of our Results of Operations and Financial Condition

Operating expenses

We classify our operating expenses into four categories: (i) research and development; (ii) sales and marketing; (iii) general and administrative; and (iv) depreciation.

Research and development. Research and development expenses consist primarily of:

- costs incurred to conduct research, such as animal research;

- costs related to the design and development of our technology, including fees paid to contract engineering firms and contract manufacturers;
- salaries and expenses, including stock-based compensation, related to our employees primarily engaged in research and development activities;
- fees paid to clinical consultants, clinical trial sites and vendors, including clinical research organizations, in preparation for clinical trials and our applications with the FDA; and
- costs related to compliance with regulatory requirements.

We recognize all research and development costs as they are incurred. Pre-clinical costs, contract engineering and design costs, patent costs and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our product into and through clinical trials, pursue additional regulatory approvals of our product in the United States, and continue commercial development of our RAP device and replaceable cartridge. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our technology may be affected by a variety of factors including: the quality of our product, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. We may not succeed in achieving all necessary regulatory approvals for our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development process or when and to what extent, if any, we will generate revenue from the commercialization and sale of our device.

Sales and Marketing

Sales and marketing expenses consist of marketing, conferences, web development, advisory boards and other miscellaneous expenses. We expect our sales and marketing expense to increase due to the anticipated growth of our business and related infrastructure as well as expanding our sales personnel, web development and other costs associated with becoming a public company.

General and administrative

General and administrative expenses consist of personnel related costs, which include salaries, as well as the costs of professional services, such as accounting and legal, facilities, information technology, stock-based compensation and other administrative expenses. We expect our general and administrative expense to increase due to the anticipated growth of our business and related infrastructure as well as accounting, insurance, investor relations and other costs associated with becoming a public company.

Depreciation

Depreciation expense consists of depreciation on our property and equipment. We depreciate our assets over their estimated useful lives. We estimate research and development equipment and lab equipment to have a 5-year life; computer equipment and software to have a 3-year life; furniture to have a 3-year life; and leasehold improvements to be depreciated over the shorter of the remaining lease term or useful lives of the asset.

Accounting for warrants

We issued warrants to purchase shares of common stock related to (i) bridge notes issued prior to its IPO, (ii) private investment in public equity ("PIPE") offerings, and (iii) as part of underwriter compensation in 2019 and 2018. We accounted for such warrants in accordance with Accounting Standards Codification (ASC) Topic 480-10, *Distinguishing Liabilities from Equity*, which identifies three categories of freestanding financial instruments that are required to be accounted for as a liability. Based on this guidance, we determined, for each issuance, that warrants did not need to be accounted for as a liability. Accordingly, the warrants were classified as equity and are not subject to remeasurement at each balance sheet date. In addition, we account for issuance costs of warrants issued with debt instruments in accordance with ASC 470-20, *Debt with Conversion and Other Options*, which states proceeds from the sale of a debt instrument with stock purchase warrants (detachable call options) are allocated to elements based on the relative fair values of the debt instrument without the warrants and of the warrants themselves at time of issuance. The portion of the proceeds so allocated to the warrants are accounted for as paid-in capital. The remainder of the proceeds are allocated to the debt instrument, which may result in a discount or premium.

On June 16, 2019, we entered into a private offering with certain institutional and accredited investors for the sale by us of 675,000 units (each a “June Unit”) of common stock issued at $14.00 per June Unit for total gross proceeds of $9,450,000. Each June Unit consisted of (i) one share of our common stock, and (ii) a warrant to purchase 0.7 shares (a total of 472,500) of common stock (each a “June Warrant”) (collectively, "June PIPE"). The offering price of the June Units was $14.00 per Unit. The June Warrants included in the June Units are exercisable at a price of $16.00 per share commencing on the date of issuance and will expire on August 23, 2024 . On July 1, 2019, we filed a Registration Statement on Form S-1 to register for resale the common stock underlying the June Units sold with our June 2019 private offering. Net proceeds from the closing of the sale of the June Units on June 19, 2019 was $8,643,302 after deducting the placement agent fees and estimated offering expenses payable by us.

On October 10, 2019, we entered into a private offering with certain institutional and accredited investors for the sale by us of 485,250 units (each an “October Unit”) of common stock issued at $12.88 per October Unit for total gross proceeds of $6,250,020. Each October Unit consisted of (i) one share of our common stock and (ii) a warrant to purchase 1.1 shares (a total of 533,775) of common stock (each an “October Warrant”) (collectively, "October PIPE"). The October Warrants included in the October Units are exercisable at a price of $12.88 per share commencing on the date of issuance and will expire on October 10, 2024. On November 8, 2019, we filed a Registration Statement on Form S-1 to register for resale the common stock underlying the October Units sold with our October 2019 private offering. We estimate the net proceeds from the closing of the sale of the October Units on October 11, 2019 was $5,738,111 after deducting the placement agent fees and estimated offering expenses payable by us.

Related registration rights agreements for each private placement are accounted for in accordance with Topic ASC Topic 450-20*Loss Contingencies*, which requires measurement of the contingent liability when an entity would be required to deliver shares under a registration payment arrangement, the transfer of consideration is probable and the number of shares to be delivered can be reasonably estimated. Accordingly, there is no liability under the payment arrangement requiring disclosure or recognition.

The fair value of warrants is estimated using the Black-Scholes option pricing model, based on the market value of the underlying common stock at the measurement dates, the contractual terms of the warrants, risk-free interest rates and expected volatility of the price of the underlying common stock. There are no expected dividends.

Stock-based compensation

Stock-based compensation transactions are recognized as compensation expense in the statements of operations based on their fair values on the date of the grant. The expense for equity awards expected to vest is recognized over the applicable vesting period of the stock award using either the straight-line method or the accelerated method, depending on the vesting structure, and is included in general and administrative expenses. We estimate the fair value of options granted using the Black-Scholes option valuation model. This estimate uses assumptions regarding a number of inputs that require us to make significant estimates and judgments. Because we are a new publicly traded common stock the expected volatility assumption was based on industry peer information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures and Changes in Internal Control over Financial Reporting

We maintain a set of disclosure controls and procedures designed to ensure that material information required to be disclosed in our filings under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that material information is accumulated and communicated to our management, including our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), as appropriate, to allow timely decisions regarding required disclosures.

Under the supervision, and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness, as of March 31, 2020, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon such evaluation, our CEO and CFO have concluded that, as of March 31, 2020, our disclosure controls and procedures were not effective. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information

required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Based on the evaluation, our management concluded that our internal controls over financial reporting were, and continue to be ineffective, as of March 31, 2020 due to material weaknesses in our internal controls arising from a lack of segregation of duties, the limitations of our financial accounting system to properly segregate duties, and the absence of internal staff with extensive knowledge of SEC financial and GAAP reporting.

Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to maintain effective segregation of duties on our assessment of our internal control over financial reporting and has concluded that the control deficiency represents a material weakness. In April 2019, an additional experienced staff was hired in the accounting and finance department. Experienced personnel will be hired in the accounting and finance department, appropriate consultants will be retained, and our accounting system will be upgraded as soon as it becomes economically feasible and sustainable. In addition, management added additional mitigating controls with regards to cash disbursements; changes were made in our authorization processes to improve segregation of duties; and we performed additional analysis and other post-closing procedures to ensure our financial statements were prepared in accordance with GAAP. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

Changes in Internal Control over Financial Reporting

We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness. Due to reductions in our spending in response to economic conditions related to the COVID-19 pandemic, funding for additional resources to further improve our system of internal controls is not planned for 2020.

Other than as described above, there has been no change in our internal control over financial reporting during our most recent calendar quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. We are not able to estimate an aggregate amount or range of reasonably possible losses for those legal matters for which losses are not probable and estimable. We have insurance policies covering potential losses where such coverage is cost effective.

We are not at this time involved in any legal proceedings.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section entitled "Risk Factors" in our 2019 Annual Report on Form 10-K, filed with the SEC, which are incorporated herein by reference. The risks described in the 2019 Annual Report on Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Except as set forth below, there have been no material changes to our risk factors from those set forth in the 2019 Annual Report on Form 10-K.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, has adversely impacted our business, including our commercial launch plans, preclinical studies and clinical trials.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 ("COVID-19"), surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices. We have also revised our commercial launch plans as a result of the overall impact on the aesthetic market, and we may be required to further revise our plans in the future based on the final impact of COVID-19.

As a result of the COVID-19 outbreak, or similar pandemics, we have and may in the future experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine,
- increased rates of non-compliance with follow-up visits with patients failing to attend their clinical trial follow-up visits or clinics closing during the scheduled visit;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of components for our device and cartridge to our contract manufacturing organization, delays in device manufacturing completion due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and

• limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or travel disruptions;

• general economic pressure on the aesthetic industry that has impacted our ability to launch our products and could further impact our ability to launch our products in the future.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and other medical device companies have been highly volatile as a result of the COVID-19 epidemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit Number	Description
10.1 +	Manufacturing Service Agreement between Soliton, Inc. and Sanmina dated March 6, 2020(incorporated by reference to exhibit 10.1 of the Company's Form 8-K filed March 11, 2020)
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*(1)	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*(1)	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	SXRL 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

* Filed herewith.

+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

(1) The certifications on Exhibit 32 hereto are deemed not “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

SOLITON, INC.

SIGNATURE	TITLE	DATE
/s/ Christopher Capelli Christopher Capelli	Chief Executive Officer, President and Director (principal executive officer)	May 14, 2020
/s/ Lori Bisson Lori Bisson	Chief Financial Officer and Executive Vice-President (principal financial and accounting officer)	May 14, 2020

Exhibit 31.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER

I, Chris Capelli, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Soliton, 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 we 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.

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.

SIGNATURE	TITLE	DATE
/s/ Christopher Capelli Christopher Capelli	Chief Executive Officer, President and Director (principal executive officer)	May 14, 2020

Exhibit 31.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER

I, Lori Bisson, certify that:

1. 1. I have reviewed this quarterly report on Form 10-Q of Soliton, 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 we 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.

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.

SIGNATURE	TITLE	DATE
/s/ Lori Bisson Lori Bisson	Chief Financial Officer and Executive Vice-President (principal financial and accounting officer)	May 14, 2020

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Soliton, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The quarterly report on Form 10-Q for the quarter ended March 31, 2020 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

SIGNATURE	TITLE	DATE
/s/ Christopher Capelli Christopher Capelli	Chief Executive Officer, President and Director (principal executive officer)	May 14, 2020

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Soliton, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The quarterly report on Form 10-Q for the quarter ended March 31, 2020 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

SIGNATURE	TITLE	DATE
/s/ Lori Bisson Lori Bisson	Chief Financial Officer and Executive Vice-President (principal financial and accounting officer)	May 14, 2020