

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 September 30, 2021

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
(State or Other Jurisdiction of
Incorporation or Organization)

3841
(Primary Standard Industrial
Classification Code Number)

36-4729076
(I.R.S. Employer Identification No.)

5304 Ashbrook Drive
Houston, Texas 77081
(Address of Principal Executive Offices) (Zip Code)
Registrant's Telephone Number, including Area Code:
(844) 705-4866

(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 periods as the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

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

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

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

The number of shares of the Company's outstanding common stock as of November 3, 2021 was 21,596,544.

	Page
PART I FINANCIAL INFORMATION	
Item 1. Financial Statements	3
Unaudited Condensed Balance Sheets as of September 30, 2021 and December 31, 2020	3
Unaudited Condensed Statements of Operations for the three and nine months ended September 30, 2021 and 2020	4
Unaudited Condensed Statements of Changes in Stockholders' Equity for the three and nine months ended September 30, 2021 and 2020	5
Unaudited Condensed Statements of Cash Flows for the nine months ended September 30, 2021 and 2020	6
Notes to the Unaudited Condensed Financial Statements	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3. Quantitative and Qualitative Disclosures About Market Risk	32
Item 4. Controls and Procedures	32
PART II OTHER INFORMATION	
Item 1. Legal Proceedings	34
Item 1A. Risk Factors	34
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	34
Item 3. Defaults Upon Senior Securities	35
Item 4. Mine Safety Disclosures	35
Item 5. Other Information	35
Item 6. Exhibits	35
Signatures	36

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

SOLITON, INC.
CONDENSED BALANCE SHEETS
(UNAUDITED)

<i>(in thousands, except for share data)</i>	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,748	\$ 31,557
Restricted cash	200	200
Total cash	21,948	31,757
Inventory	431	353
Prepaid expenses and other current assets	615	141
Total current assets	22,994	32,251
Property and equipment, net of accumulated depreciation	2,258	1,413
Intangible and other assets	318	137
Total assets	<u>\$ 25,570</u>	<u>\$ 33,801</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 671	\$ 1,008
Accrued and other current liabilities	3,531	1,812
Total current liabilities	4,202	2,820
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Common stock, \$0.001 par value, 100,000,000 authorized, 21,596,544 shares issued and outstanding at September 30, 2021 and 21,189,943 shares issued and outstanding at December 31, 2020	22	21
Additional paid-in capital	105,267	101,544
Accumulated deficit	(83,921)	(70,584)
Total stockholders' equity	21,368	30,981
Total liabilities and stockholders' equity	<u>\$ 25,570</u>	<u>\$ 33,801</u>

See accompanying notes to the unaudited condensed financial statements

SOLITON, INC.
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

<i>(in thousands, except for share and per share data)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 370	\$ —	\$ 370	\$ —
Cost of revenue	344	—	344	—
Gross profit	26	—	26	—
Operating expenses:				
Research and development	1,179	1,143	4,231	3,437
Sales and marketing	1,114	474	2,993	560
Depreciation	219	87	461	229
General and administrative	3,807	1,965	11,779	5,856
Total operating expenses	6,319	3,669	19,464	10,082
Loss from operations	(6,293)	(3,669)	(19,438)	(10,082)
Other income:				
Interest income	21	76	101	82
Gain from Additional Payment from AbbVie	6,000	—	6,000	—
Total other income	6,021	76	6,101	82
Net loss	\$ (272)	\$ (3,593)	\$ (13,337)	\$ (10,000)
Net loss per common share, basic and diluted	\$ (0.01)	\$ (0.17)	\$ (0.62)	\$ (0.55)
Weighted average number of common shares outstanding, basic and diluted	21,519,037	21,062,444	21,349,962	18,244,330

See accompanying notes to the unaudited condensed financial statements

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

<i>(in thousands)</i>	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Par			
Balance, December 31, 2020	21,190	\$ 21	\$ 101,544	\$ (70,584)	\$ 30,981
Stock-based compensation	—	—	1,036	—	1,036
Issuance of common shares	189	—	52	—	52
Net loss	—	—	—	(5,177)	(5,177)
Balance, March 31, 2021	21,379	\$ 21	\$ 102,632	\$ (75,761)	\$ 26,892
Stock-based compensation	—	—	1,410	—	1,410
Issuance of common shares	218	1	(1)	—	—
Net loss	—	—	—	(7,888)	(7,888)
Balance, June 30, 2021	21,597	\$ 22	\$ 104,041	\$ (83,649)	\$ 20,414
Stock-based compensation	—	—	1,226	—	1,226
Net loss	—	—	—	(272)	(272)
Balance, September 30, 2021	21,597	\$ 22	\$ 105,267	\$ (83,921)	\$ 21,368

<i>(in thousands)</i>	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Par			
Balance, December 31, 2019	16,932	\$ 17	\$ 66,300	\$ (56,043)	\$ 10,274
Stock-based compensation	—	—	711	—	711
Issuance of common shares	11	—	—	—	—
Net loss	—	—	—	(3,271)	(3,271)
Balance, March 31, 2020	16,943	\$ 17	\$ 67,011	\$ (59,314)	\$ 7,714
Stock-based compensation	—	—	736	—	736
Issuance of common shares	30	—	—	—	—
Issuance of common shares from June 2020 Offering, net of costs	4,217	4	32,042	—	32,046
Net loss	—	—	—	(3,136)	(3,136)
Balance, June 30, 2020	21,190	\$ 21	\$ 99,789	\$ (62,450)	\$ 37,360
Stock-based compensation	—	—	757	—	757
Net loss	—	—	—	(3,593)	(3,593)
Balance, September 30, 2020	21,190	\$ 21	\$ 100,546	\$ (66,043)	\$ 34,524

See accompanying notes to the unaudited condensed financial statements

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

	For the Nine Months Ended September 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (13,337)	\$ (10,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from Additional Payment from AbbVie	(6,000)	—
Depreciation	461	209
Stock-based compensation	3,671	2,204
Write-down of intangible asset	—	20
Changes in operating assets - (increase)/decrease:		
Inventory	(78)	(266)
Prepaid expenses and other current assets	(475)	(218)
Changes in operating liabilities - increase/(decrease):		
Accounts payable	(356)	(932)
Accrued and other current liabilities	1,719	161
NET CASH USED IN OPERATING ACTIVITIES:	(14,395)	(8,822)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Payments for the purchase of property and equipment	(1,288)	(446)
Payments for intangibles	(178)	(28)
NET CASH USED IN INVESTING ACTIVITIES:	(1,466)	(474)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common shares	52	—
Proceeds from Additional Payment from AbbVie	6,000	—
Proceeds from issuance of common shares from June 2020 Offering, net of costs	—	32,046
NET CASH PROVIDED BY FINANCING ACTIVITIES:	6,052	32,046
Net (decrease)/increase in cash, cash equivalents and restricted cash	(9,809)	22,750
Cash, cash equivalents and restricted cash, beginning of period	31,757	12,076
Cash, cash equivalents and restricted cash, end of period	\$ 21,948	\$ 34,826
<u>Supplemental cash flow disclosures:</u>		
Non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	\$ 18	\$ 249
Additions to intangible assets included in accounts payable	\$ 1	\$ —

See accompanying notes to the unaudited condensed financial stat

SOLITON, INC.

NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1 - Description of the Business, Basis of Presentation 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 its proprietary Rapid Acoustic Pulse ("RAP") technology platform. The Company is a commercial stage company with its first products having been launched for the removal of tattoos and the reduction of cellulite. The Company received clearance from the U.S. Food & Drug Administration ("FDA") for its tattoo removal indication in June of 2019 and for the temporary improvement in the appearance of cellulite in January of 2021. The Company is based in Houston, Texas. Revenue is generated by the sale of its RAP console and disposable cartridges to dermatologists and plastic surgeons, as well as med-spas under the supervision of a doctor.

Basis of Presentation

The accompanying condensed interim financial statements are unaudited. These unaudited condensed 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 generally accepted accounting principles 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, 2020 filed with the SEC on March 4, 2021. 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, 2020 unaudited condensed 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.

Summary of Significant Accounting Policies

Revenue and Related Selling Costs

Revenue is derived from the sales of the RESONIC™ system, consisting of a console and handpiece, and, from time to time, related extended warranty arrangements (collectively, "System Revenue"), and from the sale of consumable cartridge cases, each of which includes our consumable cartridges and gel pads (collectively, "Consumable Revenue") used by the Company's customers during patient treatments.

The Company recognizes revenue at the amount to which it expects to be entitled when control of the products or services is transferred to its customers. Control is generally transferred when the Company has a present right to payment and the title, and the significant risks and rewards of ownership of products or services are transferred to its customers. The Company uses contracts or customer orders to determine the existence of an arrangement. The Company's standard terms specify that title transfers upon shipment to the customer. Sales prices are documented in the executed sales contract or customer order received prior to shipment. The Company's standard terms do not allow for refunds, payments contingent upon the customer obtaining financing or other terms that could impact the customer's obligation. With the customer's initial order, where the Company has no past transaction history, the Company collects a deposit before shipment and does not recognize income until it has certainty of receipt of the cash.

Sales of its RESONIC system generally include installation and training. In most cases, consoles are sold with a limited 12 month warranty on product quality. The RESONIC console and cartridges contain enabling software that permits customers to perform patient treatments. The Company does not market this software separately from the RESONIC console or from the consumable cartridges, rather, the functionality that the software provides is part of the overall RESONIC technology. The Company markets the RESONIC system as a non-invasive aesthetic device for the improvement in the appearance of cellulite and for tattoo removal, not for its embedded software attributes included in the technology that enable its use. The Company does not provide rights to upgrades and enhancements in its contract with customers. The embedded software in the RESONIC console and cartridges is incidental to the RESONIC products as a whole and accordingly, revenue recognition is not within the scope of provisions of Accounting Standards Codification ("ASC") Topic 985.

For contracts with multiple performance obligations, each of which represent promises within a contract that are distinct, the Company allocates revenue to all distinct performance obligations based on their relative stand-alone selling prices (“SSPs”). The Company’s products and services included in its contracts with multiple performance obligations generally are not sold separately and there are no observable prices available to determine the SSP for those products and services. Since observable prices are not available, SSPs are established that reflect the Company’s best estimates of what the selling prices of the performance obligations would be if they were sold regularly on a stand-alone basis. The Company’s process for estimating SSPs without observable prices considers multiple factors that may vary depending upon the unique facts and circumstances related to each performance obligation including, when applicable, the estimated cost to provide the performance obligation, market trends in the pricing for similar offerings, product-specific business objectives, and competitor or other relevant market pricing and margins.

The Company expenses shipping and handling costs as incurred and includes them in cost of revenue. In those cases where the Company bills shipping and handling costs to customers, the Company classifies the amounts billed as System Revenue.

The Company excludes all taxes assessed by a governmental agency that are both imposed on and concurrent with the specific revenue-producing transaction from revenue (for example, sales and use taxes). In essence, the Company is reporting these amounts collected on behalf of the applicable government agency on a net basis as though they are acting as an agent. The taxes collected and not yet remitted to the governmental agency are included in accounts payable and accrued expenses in the accompanying balance sheets.

Product Warranties

Sales of the Company’s consoles and handpieces includes a limited 12 month warranty on product quality. The Company accrues warranty and related costs based on its best estimates when it determines that it is probable a charge or liability has been incurred and the amount of loss can be reasonably estimated. For new product introductions in which the Company may not have any historical experience, the Company makes estimates for warranty claims based on qualitative and quantitative information. The Company exercises judgment in estimating the expected product warranty costs, using data such as the actual and projected product failure rates, estimated repair costs, material, labor, and overhead costs. Because the Company has no historical experience with which to provide a reliable basis for estimating such warranty cost, unforeseen quality issues or component failure rates could result in future costs in excess of such estimates, or alternatively, improved quality and reliability in the Company’s products could result in actual expenses that are below those currently estimated.

Customer Payments and Incentives

The Company enters into transactions where we provide consideration in exchange for certain services provided under separate contractual arrangements. The Company accounts for such payments to customers in accordance with ASC Topic 605-50, which requires management to characterize the payment as a reduction of revenue if the Company is unable to demonstrate the receipt of a benefit that is identifiable and sufficiently separable from the revenue transaction and reasonably estimate the fair value of the benefit identified. Significant management judgment and estimates must be used to determine the fair value of the benefit received in any period.

Disaggregated Revenue

The Company disaggregates revenue based upon the nature of its products and services and the timing and in the manner which it is transferred to the customer. Substantially all revenue is recognized at the time of delivery, except for installation fees, which are recognized as work is completed. Installations do not represent a significant portion of the revenue recognized. For the three and nine months ended September 30, 2021, revenue consisted of the following (*n thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue :				
System	\$ 349	\$ —	\$ 349	\$ —
Consumable	14	—	14	—
Installation	7	—	7	—
Total revenue	\$ 370	\$ —	\$ 370	\$ —

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 unaudited condensed interim 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, the amount of warranty work to be performed for customers, the stand-alone selling price of components of our revenues, 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 and provider 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.

Merger Agreement

On May 8, 2021, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with AbbVie Inc. ("AbbVie") and Scout Merger Sub, Inc., a wholly-owned subsidiary of AbbVie ("Merger Sub"), under which Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and a wholly-owned subsidiary of AbbVie (the "Merger").

Upon the closing of the Merger, each outstanding share of Company common stock, other than shares owned by the Company, AbbVie or Merger Sub (which will be cancelled) and shares with respect to which appraisal rights are properly exercised and not withdrawn under Delaware law, will automatically be converted into the right to receive \$22.60 in cash, without interest (the "Merger Consideration").

Each stock option outstanding and unexercised immediately prior to the effective time of the Merger (the "Effective Time") will be converted into the right to receive a cash payment, without interest, in an amount equal to the excess of the Merger Consideration over the per share exercise price that would be due in cash upon exercise of such stock option. Each restricted stock unit award outstanding immediately prior to the Effective Time will be converted into the right to receive a cash payment, without interest, in an amount equal to the Merger Consideration. Each warrant to purchase Company common stock outstanding and unexercised immediately prior to the Effective Time will be converted into the right to receive a cash payment, without interest, in an amount equal to the excess of (i) the number of shares of common stock subject to the warrant, multiplied by the Merger Consideration over (ii) the number of shares of common stock subject to the warrant, multiplied by the per share exercise price of such warrant.

The consummation of the Merger is subject to certain customary closing conditions, including (i) the adoption of the Merger Agreement by the holders of a majority of the outstanding shares of the Company's common stock (the "Stockholder Approval"), (ii) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), and (iii) that no judgment or law is in effect that enjoins, makes illegal or otherwise prohibits the consummation of the Merger. Moreover, each party's obligations to consummate the Merger are subject to certain other conditions, including (a) the accuracy of the other party's representations and warranties (subject to certain materiality exceptions), (b) the other party's compliance in all material respects with its obligations under the Merger Agreement, and (c) in the case of AbbVie and Merger Sub only, (i) the absence of any pending claim, proceeding or other action by a governmental authority that seeks to prevent, prohibit or make illegal the consummation of the Merger or materially limit AbbVie's ability to own, control, direct, manage or operate the Company and (ii) the absence of any effect, change, event, development or occurrence that, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect (as defined in the Merger Agreement) that is continuing. Subject to the satisfaction of the closing conditions, closing of the Merger is expected to occur in the second half of 2021.

The Merger Agreement contains representations and warranties and covenants of the parties customary for a transaction of this nature. Until the earlier of the termination of the Merger Agreement and the Effective Time, the Company has agreed to operate its business in the ordinary course of business in all material respects and has agreed to certain other operating covenants and to not take certain specified actions prior to the consummation of the Merger, as set forth more fully in the Merger Agreement. The Company has also agreed to convene and hold a meeting of its stockholders for the purpose of obtaining the Stockholder Approval. In addition, the Merger Agreement requires that, subject to certain exceptions, the Board recommend that the Company's stockholders approve the Merger Agreement.

The Merger Agreement contains certain termination rights for the Company and AbbVie, including, among others, the right of (1) the Company to terminate the Merger Agreement in order to enter into an agreement providing for a Superior Proposal (subject to the Company's compliance with certain obligations under the Merger Agreement related to such Superior Proposal and such termination) and (2) AbbVie to terminate the Merger Agreement if the Board changes its recommendation with respect to the Merger Agreement. The Merger Agreement also provides that under specified circumstances, including in the event of termination as described in (1) or (2) above, the Company will be required to pay AbbVie a termination fee of \$18.6 million.

In connection with a termination of the Merger Agreement under specified circumstances involving failure to obtain clearance under the HSR Act to consummate the Merger (or failure to remove certain legal restraints, or to resolve certain pending claims or proceedings, arising under antitrust laws with respect to the Merger) within six months from the date of the Merger Agreement, subject to two extensions of three months each (provided other closing conditions are satisfied), or involving a non-appealable legal restraint of the Merger arising under antitrust laws, AbbVie may be required to pay the Company a reverse termination fee ("Additional Payments") of up to \$20.0 million. On September 10, 2021, AbbVie made an Additional Payment of \$6.0 million and on November 8, 2021, AbbVie made an Additional Payment of \$1.5 million and exercised its right to extend the term to consummate the Merger by an additional three months to February 8, 2022.

Material Uncertainties

The Company is an early-stage Emerging Growth Company ("EGC") and started generating revenue during the three months ended September 30, 2021. 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 and nine months ended September 30, 2021 and 2020, the Company incurred net losses of \$0.3 million and \$3.6 million, respectively, and \$13.3 million and \$10.0 million, respectively, and had net cash flows used in operating activities for the nine months ended September 30, 2021 and 2020 of \$4.4 million and \$8.8 million, respectively. At September 30, 2021, the Company had an accumulated deficit of \$83.9 million, working capital of \$18.8 million and cash, cash equivalents and restricted cash of \$21.9 million. The Company does not expect to experience positive cash flows from operating activities in the near future and anticipates incurring operating losses for the next few years as it supports the commercial launch of its products and continues to invest in research and development for additional indications in the Company's pipeline. The Company expects its cash, cash equivalents and restricted cash on hand of \$21.9 million as of September 30, 2021 and Additional Payments that have been made by AbbVie as the Merger has not been consummated by November 8, 2021 will be sufficient to fund the Company's operations for at least the next 12 months.

These factors raise uncertainties about the Company's ability to fund operations in future years. If the Company needs additional capital or financing to continue to execute its business plan or a change to 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 capital or financing will be available when needed or

that management will be able to raise capital or obtain financing on terms acceptable to the Company. The accompanying financial statements do not include any adjustments to reflect this uncertainty.

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. Unvested restricted stock awards contain dividend rights and are considered participating securities as contemplated for 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 September 30, 2021, potentially dilutive securities included options to purchase 4,266,275 common shares, warrants to purchase 529,141 common shares and unvested restricted stock of 270,850 shares.

As of September 30, 2020, potentially dilutive securities included options to purchase 3,409,550 common shares, warrants to purchase 1,324,608 common shares and unvested restricted stock of 120,842 shares.

Recent Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASC 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. Given the Company's status as an EGC, the Company may adopt this ASU in accordance with the private company guidance which has deferred the effective date to years beginning after December 15, 2021, and interim periods with fiscal years beginning after December 15, 2022. 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.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This ASU is intended to simplify various aspects related to accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and clarifying certain aspects of the current guidance to promote consistency among reporting entities. Most amendments within this ASU are required to be applied on a prospective basis, while certain amendments must be applied on a retrospective or modified retrospective basis. Given the Company's status as an EGC, the Company may adopt the amendments of this update for years beginning after December 15, 2021, and interim periods with fiscal years beginning after December 15, 2022.

The Company does not believe that these or 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' financial statements have been reclassified to conform to the current financial statement presentation. Such reclassifications had an effect on previously reported expenses between general and administrative and research and development.

Note 2 - Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (*in thousands*):

	September 30, 2021	December 31, 2020
Prepaid insurance	\$ 217	\$ 49
Prepaid software	84	52
Other prepaids and receivables	314	40
Total prepaid expenses and other current assets	<u>\$ 615</u>	<u>\$ 141</u>

As of September 30, 2021, other prepaids and receivables largely included the sale of previously purchased components used in the manufacturing of our devices back to our contract manufacturer at September 30, 2021 for \$0.3 million, payments made to vendors for work that has not yet been completed, payments made as a result of listing requirements for public companies and receivables from vendors.

Note 3 - Property and Equipment

As of September 30, 2021 and December 31, 2020, the net carrying value of property and equipment was approximately \$2.3 million and \$1.4 million, respectively, and included an amount less than \$0.1 million and \$0.7 million, respectively, of construction-in-process for equipment being built and software being developed but not yet placed into service.

Depreciation expense for the three months ended September 30, 2021 and 2020 was \$0.2 million and \$0.1 million, respectively. Depreciation expense for the nine months ended September 30, 2021 and 2020 was \$0.5 million and \$0.2 million, respectively.

Note 4 - 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 pays a nonrefundable annual maintenance fee which escalates each anniversary. Additionally, the Company agreed to a running royalty percentage of net sales in the mid-single digits. The annual maintenance fee is discontinued with the initiation of royalty payments. The specific patents initially subject to the agreement expire between 2031 and 2032.

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. For the nine months ended September 30, 2021 and 2020, the Company paid approximately \$0.1 million and \$0.1 million, respectively, for expenses related to this agreement.

As the inventor of the intellectual property licensed from MD Anderson, Dr. Capelli, the Company's Vice Chairman, Chief Science Officer and Co-Founder, 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. For the nine months ended September 30, 2021, Dr. Capelli was entitled to receive \$42.5 thousand from 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 75,000 shares issued to MD Anderson in connection with the license agreement.

Purchase Commitments

As of September 30, 2021, the Company had contractual purchase obligations for engineering and design services of \$1.6 million to Emphysys, Inc. ("Emphysys"). This commitment is for services used in the ordinary course of business and does not represent excess commitments or loss contracts. The remaining minimum purchase obligation is \$1.5 million for the 12 month period ending June 30, 2022. If we fail to spend such minimum annual amounts or if the Company terminates the addendum without cause, the Company may be required to pay Emphysys an early termination fee of no more than \$0.2 million.

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. The Company has issued purchase orders under this agreement that commit the Company to purchase \$4.8 million in manufactured goods from Sanmina.

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.

The Company entered into a manufacturing services agreement with Paramit Corporation ("Paramit") on March 22, 2021 for the production of handpieces. The agreement states that Paramit will provide the Company with certain manufactured products at prices and quantities to be agreed upon by the parties through an issued and accepted purchase order. Quantities agreed upon by both parties in an issued and accepted purchase order may only be cancelled for units to be received after the initial 60 days. The Company has issued purchase orders under this agreement that commit the Company to purchase \$0.7 million in manufactured goods from Paramit.

Lease Commitments

The Company leases space for its corporate office, which provides for an original 63 month term beginning on February 1, 2016, with initial rent payments of \$7.6 thousand per month that escalate annually to a maximum of \$8.9 thousand per month through the expiration of the agreement. On September 15, 2020, the Company entered into a 12 month extension of its corporate office lease. On November 3, 2021, the Company entered into a three month extension of its corporate office lease. Total rent expense under this office space lease arrangement for the three months ended September 30, 2021 and 2020 was \$24.8 thousand and \$24.2 thousand, respectively, and for the nine months ended September 30, 2021 and 2020 was \$73.1 thousand and \$70.8 thousand, respectively.

Future minimum lease payments as of September 30, 2021 were \$0.1 million through the lease term ending July 31, 2022.

Letter 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 September 30, 2021, the letter of credit was not used.

Legal Proceedings

From time to time, in the normal course of business, the Company may be subject to claims in legal proceedings. 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.

As previously disclosed, on May 8, 2021, the Company entered into a Merger Agreement with AbbVie and Merger Sub, pursuant to which Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and a wholly owned subsidiary of the Merger. In connection with the Merger, the following complaints have been filed against the Company and the members of the Company's board of directors: *Musanto v. Soliton, Inc., et al.*, Case No. 1:21-cv-05088 (S.D.N.Y. June 9, 2021); *Whitfield v. Soliton, Inc., et al.*, No. 1:21-cv-05330 (S.D.N.Y. June 16, 2021); *O'Guin v. Soliton, Inc., et al.*, No. 1:21-cv-05359 (S.D.N.Y. June 17, 2021); *Wiklund v. Soliton, Inc., et al.*, No. 1:21-cv-05386 (S.D.N.Y. June 18, 2021); *Boland v. Soliton, Inc., et al.*, No. 1:21-cv-05391 (S.D.N.Y. June 18, 2021); *Jabaloy v. Soliton, Inc., et al.*, No. 1:21-cv-03488 (E.D.N.Y. June 21, 2021); *Eder v. Soliton, Inc., et al.*, No. 1:21-cv-05474 (S.D.N.Y. June 22, 2021); *Post v. Soliton, Inc., et al.*, No. 1:21-cv-05496 (S.D.N.Y. June 23, 2021); *Ciccotelli v. Soliton, Inc., et al.*, No. 2:21-cv-02843 (E.D. Pa. June 25, 2021); *Walker v. Soliton, Inc., et al.*, No. 1:21-cv-00928 (D. Del. June 29, 2021); *Sheridan v. Soliton, Inc., et al.*, No. 1:21-cv-05656 (S.D.N.Y. June 30, 2021); *Siljanovski v. Soliton, Inc., et al.*, No. 1:21-cv-05935 (S.D.N.Y. July 9, 2021) (collectively, the "Complaints"). Each of the Complaints asserted claims under Sections 14(a) and 20(a) of the Exchange Act,

and Rule 14a-9 promulgated thereunder, alleging that the Company's Definitive Proxy Statement on Schedule 14A (the "Definitive Proxy Statement") with respect to the special meeting of the Company's stockholders held on July 20, 2021 omitted to disclose certain facts. In addition, the *Musanto* Complaint alleged that the named directors of the Company breached their fiduciary duties by approving the Merger Agreement through a flawed and unfair process and by failing to not make complete and accurate disclosures regarding this process and that the Company aided and abetted the alleged breaches. Each of the Complaints sought to enjoin or rescind the Merger and requests attorneys' fees and damages in an unspecified amount. The Company also received a demand for books and records pursuant to Section 220 of the Delaware General Corporation Law. The demand sought books and records related to the Merger, the independence and disinterestedness of the Company's board of directors and the Definitive Proxy Statement in order to investigate whether any wrongdoing or mismanagement took place in connection with the Merger. While the Company believed that the Complaints lacked merit and that the disclosures set forth in the Definitive Proxy Statement complied fully with applicable law, the Company determined to voluntarily supplement the Definitive Proxy Statement, as set forth in the Company's Schedule 14A filed with the SEC on July 15, 2021, solely to avoid the expense, burden and risk associated with any litigation matter.

Employment Arrangements

The Company has employment agreements with certain employees to provide benefits, including salary and other wage-related benefits, in the event of termination. In addition, the Company has adopted a severance policy for certain key members of executive management to provide certain benefits, including salary and other wage-related benefits, in the event of termination without cause. On May 8, 2021, the Board approved an amendment to the severance policy to cover all employees. In total, given the amendments to employee agreements, these benefits would amount to \$5.1 million using the rate of compensation in effect at September 30, 2021.

On May 8, 2021, the Board approved the granting of retention bonuses to certain non-executive employees for an amount equal to (a) three months of annual salary, if the Merger has a closing or termination date that is on or prior to November 8, 2021, or (b) six months of annual salary, if the Merger has a closing or termination date that is after November 8, 2021. As such, the Company is committed to pay six months of annual salary in the amount of \$0.7 million as the Merger will close or terminate after November 8, 2021.

Note 5 - Stockholders' Equity

2018 Stock Plan

In June 2018, the Company's Board of Directors (the "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 was 5,650,000 shares as of September 30, 2021, including an increase of 1,500,000 shares, which was approved by the Company's shareholders at the annual shareholders meeting in April 2021. As of September 30, 2021, 1,198,725 shares remained available for grant under the 2018 Stock Plan.

Restricted Stock

Restricted stock activity for the nine months ended September 30, 2021 is summarized as follows:

	Number of Shares	Weighted- Average Grant Date Fair Value
Outstanding, December 31, 2020	308,344	\$ 8.70
Vested	(37,494)	11.54
Outstanding, September 30, 2021	<u>270,850</u>	<u>\$ 8.31</u>

During the three and nine months ended September 30, 2021 and 2020, the Company recorded \$0.2 million and \$0.1 million, respectively, and \$0.6 million and \$0.4 million, respectively, in stock-based compensation for the restricted shares previously issued.

As of September 30, 2021, there was \$1.9 million of unrecognized compensation expense related to restricted shares.

Stock Options

The following table summarizes stock option activities for the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2020	3,919,550	\$ 4.47	8.11	\$ 13,095
Granted	411,650	9.74		
Forfeited	(64,925)	4.37		
Outstanding, September 30, 2021	4,266,275	\$ 4.98	7.56	\$ 65,619
Exercisable, September 30, 2021	2,360,925	\$ 3.10	6.91	\$ 40,741

During the nine months ended September 30, 2021, the Company granted certain individuals options to purchase 411,650 shares of common stock with an average exercise price of \$9.74 per share, a contractual term of ten years, and a vesting period of 25.00% per year over four years. The options had an aggregate grant date fair value of \$5.1 million that was calculated using the Black-Scholes option pricing model. Variables used in the Black-Scholes option pricing model included: (1) discount rate ranging from 0.19% to 1.03% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected life of 6.25 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility ranging from 88.90% to 90.77% based on the historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair value of the Company's stock ranging from \$9.74 to \$16.47 per share.

All options issued and outstanding are being amortized over their respective vesting periods. During the three and nine months ended September 30, 2021 and 2020, the Company recorded option expense of \$1.0 million and \$0.6 million, respectively and \$3.0 million and \$1.8 million, respectively. Unrecognized compensation expense for options at September 30, 2021 was \$9.7 million.

Warrants

The following table summarizes warrant activity for the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2020	1,324,608	\$ 11.32	3.44	\$ —
Exercised	(406,601)	8.20	—	4,945
Forfeited (cashless exercise)	(388,866)	13.55	—	—
Outstanding, September 30, 2021	529,141	\$ 12.08	2.69	\$ 4,384
Exercisable, September 30, 2021	529,141	\$ 12.08	2.69	\$ 4,384

Note 6 - Subsequent Events

The Merger and Hart-Scot-Rondino Antitrust Improvements Act of 1976 (the "HSR Act")

On August 6, 2021, the Company and AbbVie each received a request for additional information and documentary material (the "Second Request") from the FTC in connection with the FTC's review of the transactions contemplated by the Merger Agreement. The effect of the Second Request is to extend the waiting period imposed by the HSR Act until 30 days after the Company and AbbVie have certified substantial compliance with the Second Request, unless that period is extended voluntarily by the parties or terminated sooner by the FTC. The Company and AbbVie continue to work cooperatively with the FTC staff

in its review of the proposed transaction, and continue to expect to complete the transaction in the fourth quarter of 2021, subject to the satisfaction or permitted waiver of the conditions to closing.

On November 8, 2021, AbbVie made another Additional Payment of \$1.5 million and exercised its right to extend the term to consummate the Merger by an additional three months to February 8, 2022.

As of November 12, 2021, both the Company and AbbVie had submitted their responses to the Federal Trade Commission's ("FTC") request for additional information in connection with the FTC's review of the transactions contemplated by the Merger Agreement.

On November 5, 2021, the FDA cleared the 510(k) application the Company submitted on August 9, 2021 for long-term improvement in the appearance of cellulite.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

References in this Form 10-Q to "we," "us," "its," "our" or the "Company" are to Soliton, Inc. ("Soliton"), as appropriate to the context.

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, 2020 filed with the SEC on March 4, 2021 (the "2020 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 2020 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") device for tattoo removal and cellulite reduction, to develop the RAP device for other indications and develop our dermatological technologies;
- the timing of our national rollout, which we expect to occur in mid-2022 and is subject to the successful completion of our initial limited launch;
- 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;

- our sales and marketing capabilities;
- potential product liability claims;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to obtain all parts required to manufacture the RAP device, handpiece and cartridge;
- 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 affects spending on cosmetic procedures;
- volatility in the market price of our stock;
- potential dilution to current stockholders from the issuance of equity awards; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.
- Risks associated with the May 8, 2021 Agreement and Plan of Merger (the "Merger Agreement") with AbbVie Inc. ("AbbVie") and Scout Merger Sub, Inc., a wholly owned subsidiary of AbbVie ("Merger Sub"), under which Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and a wholly-owned subsidiary of AbbVie (the "Merger"), including:
 - the risk that the proposed Merger may not be completed in a timely manner or at all;
 - the failure to satisfy any of the conditions to the consummation of the proposed Merger, including the receipt of certain governmental and regulatory approvals;
 - the occurrence of any event, change or other circumstance that could give rise to the termination of the Merger Agreement; and
 - the outcome of any legal proceedings that have been or may be instituted against the Company related to the Merger Agreement or the proposed Merger.

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, level 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 RAP. We are an early-stage commercial company with our

first products recently launching for the removal of tattoos and the reduction of cellulite. Our RAP device uses rapid pulses of designed acoustic shockwaves to disrupt cellular structures in the dermal and subdermal tissue. The uniqueness of our designed shockwave allows us to target the differential in stiffness between cellular structures and physically change those structures non-invasively which we believe represents a platform technology potentially useful in tattoo removal and cellulite treatment, for which we have received FDA clearance and fibrotic scar treatment, which has not yet received FDA clearance. We believe the high repetition rate, rapid rise and fall of the wave, and significant peak pressure delivered in a non-focused manner make our shockwave significantly different from other available shockwave technologies. Importantly, our technology allows the disruption of targeted structures within the skin with only minimal discomfort and without additional treatment-related downtime for tattoo removal or any downtime for cellulite treatment.

We received clearance for our initial device from the U.S. Food and Drug Administration ("FDA") on May 24, 2019 allowing our device to be used as an accessory to the 1064 nm Q-switched laser for black ink tattoo removal on patients with skin tones on the Fitzpatrick Skin Type scale between I and III. When used in conjunction with existing lasers for tattoo removal, our technology allows a doctor to treat a patient multiple times in a single office visit and significantly reduces the number of office visits required to remove a tattoo, allowing a dramatic acceleration of the tattoo removal process. In January 2021, we received additional clearance from the FDA for temporary improvement in the appearance of cellulite. Used on a stand-alone basis, our technology generates, on average, an approximate 30% reduction in the cellulite severity score ("CSS") for subjects in a single treatment without breaking the skin. RAP cellulite treatments cause only minimal discomfort, do not require anesthesia and do not result in any significant treatment-related side effects or patient downtime.

We launched our RAP device for tattoo removal and cellulite reduction in September 2021, initiating the first shipments into select cosmetic dermatology and plastic surgery offices. We expect to continue to place devices and train accounts during the fourth quarter of 2021. We experienced delays in our launch timing due to the focus of our resources being divided between the launch and managing the Merger. Further, we had certain delays in the manufacturing and final test process of the initial devices driven primarily by the impact of COVID-19 on our software development team based in India and certain suppliers' ability to provide timely components. We generate revenue from both the initial sale of the device and from the recurring sales of disposable cartridges that are required by the device to deliver the various therapies. We refer to this as our "razor and blade" recurring revenue model. Cartridges are designed to be specific to the intended procedure and each treatment session requires one or more cartridges. One tattoo cartridge can facilitate up to four standard laser treatment passes in a single office visit for the average-sized tattoo (about the size of a deck of playing cards). Therefore, a patient with an average-sized tattoo that requires three office visits will require the use of three cartridges. One cellulite cartridge will treat one leg and buttocks area in a single session for an average patient. As such, most cellulite patients will require two cartridges for their initial treatment of both legs and buttocks. We anticipate that patients may benefit from a second maintenance treatment using a single cartridge across the full treatment area, but have not yet demonstrated this in clinical trials. We intend to begin a multi-site study in the fourth quarter of 2021, which will study the effect of multiple treatments in subjects with cellulite.

We also have ongoing clinical programs in several indications, which, if successful, will allow us to expand commercialization of our products into additional markets. As a stand-alone device, we believe RAP has the potential to reduce the effects of fibrosis and stimulate beneficial fibroblast behavior. This capability enables the targeting of fibrotic (keloid and hypertrophic) scars, as well as smoothing and tightening skin. Importantly, we are planning to initiate a collaborative study with the Navy of our RAP device in the treatment of keloid and hypertrophic scars in 2021. Further before the end of 2021, we plan to initiate additional clinical work in tattoo removal with multi-colored ink tattoos and to demonstrate the effect of multiple treatments in the improvement in the appearance of cellulite. We announced results from a study in mice demonstrating the ability of RAP to significantly reduce liver fibrosis, further validating the scientific basis for RAP's mechanism of action and potentially widening the range of indications for which RAP may be suitable. Our technology has not been cleared by the FDA for the treatment of scars or fibrosis.

Commercial upgrades to our Generation 2.0 device to improve usability were subsequently approved through a Special 510(k) in March 2020. This improved device was utilized in our recently completed pivotal cellulite trial, the data from which was included in the 510(k) pre-market application of our Generation 2.0 device for the temporary reduction in the appearance of cellulite filed on June 30, 2020 and approved in January of 2021. Further commercial upgrades to our Generation 2.0 device were approved through a Special 510(k) in April of 2021, clearing the regulatory path to the launch of our first commercial devices. We filed a 510(k) pre-market application with the FDA August 9, 2021, seeking to extend our claims to include the long-term improvement in the appearance of cellulite. On November 5, 2021, the FDA cleared this application. We also intend to secure regulatory approval in international markets and are currently developing a regulatory strategy for these markets.

Our ongoing research and development activities are primarily focused on optimizing the commercial device and cartridge design for tattoo removal and cellulite reduction 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.

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 compete with many other technologies for consumer demand. Further, the aesthetic industry in which we operate is particularly vulnerable to economic trends. The decision to undergo a RESONIC procedure is driven by consumer demand. Procedures performed using our systems are 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 operate.

Recent Developments

On November 5, 2021, the FDA cleared the 510(k) application we submitted on August 9, 2021 for long-term improvement in the appearance of cellulite. The results from our 52-week follow-up visit in our pivotal cellulite study were provided to the FDA to support this application. At 52 weeks, all participants found their treatment areas to appear improved compared to the pre-treatment photos and 97.6% of participants found there was good improvement in the appearance of cellulite.

Agreement and Plan of Merger

On May 8, 2021, we entered into the Merger Agreement with AbbVie and Merger Sub, under which Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and a wholly-owned subsidiary of AbbVie.

Upon the closing of the Merger, each outstanding share of our common stock, other than shares owned by us, AbbVie or Merger Sub (which will be cancelled) and shares with respect to which appraisal rights are properly exercised and not withdrawn under Delaware law, will automatically be converted into the right to receive \$22.60 in cash, without interest (the "Merger Consideration").

Each stock option outstanding and unexercised immediately prior to the effective time of the Merger (the "Effective Time") will be converted into the right to receive a cash payment, without interest, in an amount equal to the excess of the Merger Consideration over the per share exercise price that would be due in cash upon exercise of such stock option. Each restricted stock unit award outstanding immediately prior to the Effective Time will be converted into the right to receive a cash payment, without interest, in an amount equal to the Merger Consideration. Each warrant to purchase our common stock outstanding and unexercised immediately prior to the Effective Time will be converted into the right to receive a cash payment, without interest, in an amount equal to the excess of (i) the number of shares of common stock subject to the warrant, multiplied by the Merger Consideration over (ii) the number of shares of common stock subject to the warrant, multiplied by the per share exercise price of such warrant.

The consummation of the Merger is subject to certain customary closing conditions, including (i) the adoption of the Merger Agreement by the holders of a majority of the outstanding shares of our common stock, (ii) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), and (iii) that no judgment or law is in effect that enjoins, makes illegal or otherwise prohibits the consummation of the Merger. Moreover, each party's obligations to consummate the Merger are subject to certain other conditions, including (a) the accuracy of the other party's representations and warranties (subject to certain materiality exceptions), (b) the other party's compliance in all material respects with its obligations under the Merger Agreement, and (c) in the case of AbbVie and Merger Sub only, (i) the absence of any pending claim, proceeding or other action by a governmental authority that seeks to prevent, prohibit or make illegal the consummation of the Merger or materially limit AbbVie's ability to own, control, direct, manage or operate us and (ii) the absence of any effect, change, event, development or occurrence that, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect (as defined in the Merger Agreement) that is continuing. Subject to the satisfaction of the closing conditions, closing of the Merger is expected to occur in the second half of 2021.

The Merger Agreement contains representations and warranties and covenants of the parties customary for a transaction of this nature. Until the earlier of the termination of the Merger Agreement and the Effective Time, we have agreed to operate our business in the ordinary course of business in all material respects and have agreed to certain other operating covenants and to not take certain specified actions prior to the consummation of the Merger, as set forth more fully in the Merger Agreement.

The Merger Agreement contains certain termination rights for us and AbbVie, including, among others, the right of (1) the Company to terminate the Merger Agreement in order to enter into an agreement providing for a Superior Proposal (subject to

our compliance with certain obligations under the Merger Agreement related to such Superior Proposal and such termination) and (2) AbbVie to terminate the Merger Agreement if the Board changes its recommendation with respect to the Merger Agreement. The Merger Agreement also provides that under specified circumstances, including in the event of termination as described in (1) or (2) above, we will be required to pay AbbVie a termination fee of \$18.6 million.

In connection with a termination of the Merger Agreement under specified circumstances involving failure to obtain clearance under the HSR Act to consummate the Merger (or failure to remove certain legal restraints, or to resolve certain pending claims or proceedings, arising under antitrust laws with respect to the Merger) within six months from the date of the Merger Agreement, subject to two extensions of three months each (provided other closing conditions are satisfied), or involving a non-appealable legal restraint of the Merger arising under antitrust laws, AbbVie may be required to pay us a reverse termination fee ("Additional Payments") of up to \$20.0 million. As of November 12, 2021, AbbVie had paid us Additional Payments of \$17.5 million and had exercised its right to extend the period to consummate the Merger by three months to February 8, 2022.

On July 20, 2021, we held a special meeting of our stockholders in Houston, Texas. At this meeting, our stockholders adopted the Merger Agreement.

Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act") Filing

The Merger is subject to the requirements of the HSR Act, which provides that the Merger may not be completed until the applicable waiting period under the HSR Act is terminated or expires. On June 2, 2021, the Company and AbbVie filed the requisite notification and report forms under the HSR Act with the Antitrust Division of the Department of Justice and the Federal Trade Commission (the "FTC"). Following informal discussions with the staff at the FTC, AbbVie and the Company have agreed to voluntarily provide the FTC with additional time in which to review the Merger. On July 2, 2021, AbbVie, as the acquiring party, voluntarily withdrew its pre-merger notification and report form under the HSR Act. In accordance with the regulations under the HSR Act, AbbVie resubmitted its HSR Act filing on July 7, 2021, commencing a new 30-day waiting period under the HSR Act, which expired at 11:59 p.m. ET on August 6, 2021. Withdrawing and refiling pre-merger notifications is a standard procedure in order to provide additional time for antitrust review of certain transactions. The Company and AbbVie continue to work cooperatively with the FTC staff in their review of the proposed transaction and continue to expect to complete the transaction in the second half of 2021, subject to the satisfaction or permitted waiver of the conditions to closing.

On August 6, 2021, the Company and AbbVie each received a request for additional information and documentary material (the "Second Request") from the FTC in connection with the FTC's review of the transactions contemplated by the Merger Agreement. The effect of the Second Request is to extend the waiting period imposed by the HSR Act until 30 days after the Company and AbbVie have certified substantial compliance with the Second Request, unless that period is extended voluntarily by the parties or terminated sooner by the FTC. The Company and AbbVie continue to work cooperatively with the FTC staff in its review of the proposed transaction and continue to expect to complete the transaction in the fourth quarter of 2021, subject to the satisfaction or permitted waiver of the conditions to closing.

As of November 12, 2021, both the Company and AbbVie had submitted their responses to the Federal Trade Commission's ("FTC") request for additional information in connection with the FTC's review of the transactions contemplated by the Merger Agreement.

Results of Operations for the Three and Nine Months Ended September 30, 2021 Compared to the Three and Nine Months Ended September 30, 2020

Revenue

We generate revenue primarily from sales of our RESONIC system and from sales of consumables to our customers. We initiated the initial launch of the RESONIC technology in September 2021. We generated revenue of \$0.4 million for each of the three and nine months ended September 30, 2021, compared to zero for each of the same prior year periods. A majority of these devices placed in the period had terms which allowed the practice to pay for the device in installments. As we have no historical perspective with which to estimate probability of collection, we have deferred the revenue recognition on the unpaid balances. As of September 30, 2021, \$0.3 million in revenue for the devices placed in service had not yet been recognized.

Revenue (in thousands, except for percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	Change (\$)	Change (%)	2021	2020	Change (\$)	Change (%)
Revenue:								
System	\$ 356	\$ —	\$ 356	100.0 %	\$ 356	\$ —	\$ 356	100.0 %
Consumable	14	—	14	100.0 %	14	—	14	100.0 %
Total revenue	<u>\$ 370</u>	<u>\$ —</u>	<u>\$ 370</u>	<u>100.0 %</u>	<u>\$ 370</u>	<u>\$ —</u>	<u>\$ 370</u>	<u>100.0 %</u>

Overall, we experienced an increase in revenue solely as a result the initiation of our limited launch in September 2021.

Our business plan focuses near-term on placing the remaining planned systems at customers during our limited launch and properly supporting these key accounts through the limited launch period. We plan to use the patient experience and physician support garnered during the limited launch to execute a national roll-out beginning in mid-2022. As we gain broader distribution, we will focus on increasing our consumable revenue by driving demand for cellulite and tattoo removal procedures through targeted marketing programs. We anticipate that as we continue to implement our business plan and expand our installed base our consumable revenue will increase as a percentage of our total revenue.

System revenue. Sales of our RESONIC system include the RESONIC control unit and RESONIC handpiece. Our standard terms do not allow for trial or evaluation periods, rights of return, or refund payments contingent upon the customer obtaining financing or other terms that could impact the customer's obligation. System revenue, including installation revenue, increased by \$0.4 million for the three and nine months ended September 30, 2021, as compared to the same periods in 2020. This increase is attributable to the initiation of our commercial launch in September 2021. System revenue represented 96.2% of our total revenue for the three and nine months ended September 30, 2021, respectively.

Consumable revenue. We generate consumable revenue through sales of cases of consumable treatment cartridges, each of which includes our consumable cartridges and gel pads, which are used by our customer during treatments. Our average selling price for cartridges is influenced by procedure type mix between tattoo and cellulite and was significantly impacted by the cartridges initially provided at no cost to accounts purchasing the device. Consumable revenue increased by \$14.0 thousand for the three and nine months ended September 30, 2021, as compared to the same periods in 2020. The increase in consumable revenue was due to the initiation of our commercial launch in September 2021. Consumable revenue accounted for 3.8% of our total revenue for the three and nine months ended September 30, 2021, respectively.

Cost of Revenue and Gross Profit (in thousands, except for percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	Change (\$)	Change (%)	2021	2020	Change (\$)	Change (%)
Cost of revenue:								
System	\$ 327	\$ —	\$ 327	100.0 %	\$ 327	\$ —	\$ 327	100.0 %
Consumable	17	—	17	100.0 %	17	—	17	100.0 %
Total cost of revenue	\$ 344	\$ —	\$ 344	100.0 %	\$ 344	\$ —	\$ 344	100.0 %
% of total revenue	93.0 %				93.0 %			
Gross profit (loss):								
System	\$ 29	\$ —	\$ 29	100.0 %	\$ 29	\$ —	\$ 29	100.0 %
Consumable	(3)	—	(3)	100.0 %	(3)	—	(3)	100.0 %
Total gross profit	\$ 26	\$ —	\$ 26	100.0 %	\$ 26	\$ —	\$ 26	100.0 %
Gross profit %	7.0 %				7.0 %			

Gross profit as a percentage of revenue typically fluctuates with product and regional mix, selling prices, material costs and revenue levels. The gross profit as a percentage of revenue for the three and nine months ended September 30, 2021 increased compared to the same period in 2020 due entirely to the fact that no gross margin had been recognized prior to the initiation of our initial launch in September 2021. Gross profit for the three and nine months ended September 30, 2021 was negatively impacted by higher than expected shipping costs to expedite devices to accounts and significant material scrap costs experienced during the initiation of product manufacturing.

Operating Expenses (in thousands, except for percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	Change (\$)	Change (%)	2021	2020	Change (\$)	Change (%)
Operating expenses								
Research and development	\$ 1,179	\$ 1,143	\$ 36	3.15 %	\$ 4,231	\$ 3,437	\$ 794	23.10 %
Sales and marketing	1,114	474	640	135.02 %	2,993	560	2,433	434.46 %
Depreciation	219	87	132	151.72 %	461	229	232	101.31 %
General and administrative	3,807	1,965	1,842	93.74 %	11,779	5,856	5,923	101.14 %
Total operating expenses	\$ 6,319	\$ 3,669	\$ 2,650	72.23 %	\$ 19,464	\$ 10,082	\$ 9,382	93.06 %

Three months ended September 30, 2021:

Research and development. Research and development expenses increased by less than \$0.1 million compared to the same period in 2020, mainly due to increases in salaries and related costs of \$0.1 million and engineering related costs of \$0.2 million offset by decreases in expenses for animal research of \$0.2 million, clinical trials and licenses and other IP of \$0.1 million.

Sales and marketing. Sales and marketing expenses increased by \$0.6 million compared to the same period in 2020, largely attributed to increases in expenses for salaries and related costs (including stock-based compensation) of \$0.6 million and marketing costs to support the launch of our products of \$0.3 million offset by decreases in training and support expenses of \$0.3 million.

General and administrative. General and administrative expenses increased by \$1.8 million compared to the same period in 2020. This increase was primarily due to increases in professional fees and expenses associated with the Merger of \$0.8 million, stock-based compensation of \$0.5 million, and salaries and related costs of \$0.6 million offset by decreases in other expenses of \$0.1 million.

Nine months ended September 30, 2021:

Research and development. Research and development expenses increased by \$0.8 million compared to the same period in 2020, mainly due to increases in expenses for salaries and related costs of \$0.4 million and engineering related costs of \$0.4 million.

Sales and marketing. Sales and marketing expenses increased by \$2.4 million compared to the same period in 2020, largely attributed to increases in expenses for salaries and related costs (including stock-based compensation) of \$1.6 million and marketing costs to support the launch of our products of \$0.8 million.

General and administrative. General and administrative expenses increased by \$5.9 million compared to the same period in 2020. This increase was primarily due to increases in professional fees and expenses associated with the Merger of \$3.4 million, stock-based compensation of \$1.3 million, salaries and related costs of \$1.1 million and other costs of \$0.1 million.

Liquidity and Capital Resources

On September 30, 2021, we had \$21.7 million of cash and cash equivalents and \$0.2 million in restricted cash supporting a letter of credit benefiting our contract manufacturer.

We began to generate revenue in September of 2021 having completed the commercialization of our RAP units and initiated sales of the units and consumable cartridges. We expect to continue to invest in the commercial launch of our products and our research and development efforts to support our current initiatives.

We estimate our current cash, cash equivalents and restricted cash resources of \$21.9 million at September 30, 2021, which includes Additional Payments made by AbbVie of \$6.0 million, and incremental Additional Payments and extension fee payments of \$11.5 million because the Merger had not been consummated by November 8, 2021, are sufficient to fund our operations for at least the next 12 months. We anticipate incurring operating losses for the next several years as we complete the development of our products, seek requested regulatory clearances to market such products and support the commercial launch of our products. These factors raise uncertainties about our ability to fund operations in future years. If we need to raise additional capital in order to continue to execute our business plan, including commercializing and generating revenues from products with existing regulatory clearances and obtaining additional regulatory clearance for our products currently 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 us. A failure to raise sufficient capital could adversely impact our ability to achieve our intended business objectives and meet our financial obligations as they become due and payable.

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. We are able to remain open but have required our employees to work from home for a portion of the work week. We have experienced interruptions in our supply chain due to global part shortages, supply chain limitations, and labor shortages from COVID-19. Due to many uncertainties, we are 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 nine months ended September 30, 2021 and 2020, respectively *(in thousands)*:

	2021	2020
Net cash used in operating activities	\$ (14,395)	\$ (8,822)
Net cash used in investing activities	(1,466)	(474)
Net cash provided by financing activities	6,052	32,046
Net (decrease)/increase in cash	\$ (9,809)	\$ 22,750

Cash Flows for the nine months ended September 30, 2021 and 2020

Operating activities. Net cash used in operating activities was \$14.4 million during the nine months ended September 30, 2021 and consisted of a net loss of \$13.3 million and a gain from an Additional Payment from AbbVie of \$6.0 million offset by a net change in operating assets and liabilities of \$0.8 million and non-cash items of \$4.1 million. The change in operating assets and liabilities included sources of cash from increases in accrued liabilities of \$1.7 million offset mainly by the use of

cash for increases in inventory of \$0.1 million, prepaid expenses and other current assets of \$0.5 million and a decrease in accounts payable of \$0.4 million. The increase in accrued expenses was driven primarily by increased professional fees and other costs associated with the Merger and sales and marketing expenses as we prepared for our launch. The decrease in inventory was driven by the sale of previously purchased components back to our contract manufacturer. The change in prepaid expenses, including other prepaids and receivables, was largely driven by the sale of previously purchased components used in the manufacture of our devices back to our contract manufacturer at September 30, 2021, new insurance policies, reporting software for public companies and prepayments for work that had not yet been performed by contractors by September 30, 2021. Non-cash items consisted of stock-based compensation of \$3.7 million and depreciation expense of \$0.4 million.

Net cash used in operating activities was \$8.8 million during the nine months ended September 30, 2020 and consisted of a net loss of \$10.0 million and a net change in operating assets and liabilities of \$1.2 million offset by non-cash items of \$2.4 million. The change in operating assets and liabilities included a use of cash for prepaid expenses and other current assets of \$0.2 million, inventory of \$0.3 million and accounts payable of \$0.9 million offset by an increase in accrued liabilities of \$0.2 million. 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 September 30, 2020. The decrease in accounts payable was mainly due to an increase in invoices received at December 31, 2019 from a few of our largest vendors. The amounts owed to such vendors were not of the same magnitude at September 30, 2020. The increase in accrued liabilities was driven primarily by a few vendors focused on expanding our brand identity and building our brand website during the period. Non-cash items consisted of stock-based compensation of \$2.2 million and depreciation expense of \$0.2 million.

Investing activities. Net cash used in investing activities for the nine months ended September 30, 2021 was \$1.5 million compared to \$0.5 million for the same period in 2020. The increase in net cash used was primarily due to \$0.9 million utilized towards the purchase of property and equipment primarily as a result of the investment in our research equipment and tooling as we prepared for our launch.

Financing activities. Net cash provided by financing activities during the nine months ended September 30, 2021 was \$6.1 million compared to \$32.0 million for the same period in 2020. The \$6.1 million in 2021 was a result of net proceeds from AbbVie for \$6.0 million for Additional Payments and \$0.1 million for the exercise of warrants for cash during the period compared to \$32.0 million for the same period in 2020 due to cash proceeds received from our June 2020 Offering.

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. Additionally, we agreed to a running royalty percentage of net sales in the mid-single digits. The annual maintenance fee is discontinued with the initiation of royalty payments. 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 advance 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. For the nine months ended September 30, 2021 and 2020, we paid approximately \$0.1 million and \$0.1 million, respectively, for expenses related to this agreement.

As the inventor of the intellectual property licensed from MD Anderson, Dr. Capelli, our Vice Chairman, Chief Science Officer and Co-Founder, 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. For the nine months ended September 30, 2021, Dr. Capelli was entitled to receive \$42.5 thousand from 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

As of September 30, 2021, we had contractual purchase obligations for engineering and design services of \$1.6 million to Emphysys, Inc. ("Emphysys"). This commitment is for services used in the ordinary course of business and does not represent excess commitments or loss contracts. The remaining minimum purchase obligation is \$1.5 million for the 12 month period ending June 30, 2022. If we fail to spend such minimum annual amounts or if the Company terminates the Addendum without cause, the Company may be required to pay Emphysys an early termination fee of no more than \$0.2 million.

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. We have issued purchase orders under this agreement that commit us to purchase \$4.8 million in manufactured goods from Sanmina.

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.

We entered into a manufacturing services agreement with Paramit Corporation ("Paramit") on March 22, 2021 for the production of handpieces. The agreement states that Paramit will provide us with certain manufactured products at prices and quantities to be agreed upon by the parties through an issued and accepted purchase order. Quantities agreed upon by both parties in an issued and accepted purchase order may only be cancelled for units to be received after the initial 60 days. We have issued purchase orders under this agreement that commit us to purchase \$0.7 million in manufactured goods from Paramit.

Lease Commitments

We lease space for our corporate office, which lease provides for an original 63 month term beginning on February 1, 2016, with initial rent payments of \$7.6 thousand per month that escalate annually to a maximum of \$8.9 thousand per month through the expiration of the agreement. On September 15, 2020, we entered into a 12 month extension of our corporate office lease. On November 3, 2021, we entered into a three month extension of our corporate office lease. 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 September 30, 2021 were \$0.1 million through the lease term ending July 31, 2022.

Employment Arrangements

The Company has employment agreements with certain employees to provide benefits, including salary and other wage-related benefits, in the event of termination. In addition, the Company has adopted a severance policy for certain key members of executive management to provide certain benefits, including salary and other wage-related benefits, in the event of termination without cause. On May 8, 2021, the Board approved an amendment to the severance policy to cover all employees. In total, given the amendments to employee agreements, these benefits would amount to \$5.1 million using the rate of compensation in effect at September 30, 2021.

On May 8, 2021, the Board approved the granting of retention bonuses to certain non-executive employees for an amount equal to (a) three months of annual salary, if the Merger has a closing or termination date that is on or prior to November 8, 2021, or (b) six months of annual salary, if the Merger has a closing or termination date that is after November 8, 2021. As such, the Company is committed to pay six months of annual salary in the amount of \$0.7 million as the Merger will close or terminate after November 8, 2021.

Amendment to Brad Hauser Employment Agreement

In connection with the execution of the Merger Agreement, on May 8, 2021, we entered into an amendment (the "Employment Agreement Amendment") to that certain Employment Agreement, dated October 30, 2020, between the Company and its Chief Executive Officer, Brad Hauser (the "Employment Agreement"). The Employment Agreement Amendment provides that, if Mr. Hauser becomes entitled to payments and/or benefits under the Employment Agreement or otherwise (collectively, the "Total Payments") that would result in Mr. Hauser being subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), Mr. Hauser will be entitled to receive a gross-up payment in an amount such that, after payment by Mr. Hauser of all applicable taxes on the gross-up payment (including any excise tax and any associated interest charges or penalties that could be imposed under Section 4999 of the Code), Mr. Hauser will retain an amount of the gross-up payment equal to the excise tax and any associated interest charges or penalties imposed by Section 4999 upon the Total Payments, such that the net amount retained by Mr. Hauser shall be equal to the net amount of the Total Payments as if the excise tax imposed by Section 4999 was not applicable to the Total Payments, provided that the amount of the gross-up payment to Mr. Hauser will not exceed \$250,000.

Non-Competition and Non-Solicitation Agreement with Mr. Hauser

On May 8, 2021, in connection with the execution of the Merger Agreement, we entered into a non-competition and non-solicitation agreement with Mr. Hauser (the "Non-Competition Agreement"). The Non-Competition Agreement provides that, subject to certain exceptions set forth therein, during Mr. Hauser's employment with us and until 18 months following the Closing, Mr. Hauser will be prohibited from, directly or indirectly, including on behalf of any person, firm or other entity, (i) actively soliciting for employment any employee of the Company or any of its parents, subsidiaries, divisions or affiliates, or anyone who was an employee of the Company or one of its parents, subsidiaries, divisions or affiliates within the six-month period prior to the Closing, or inducing any such employee to terminate his or her employment with the Company or any of its parents, subsidiaries, divisions or affiliates, (ii) performing services for any other business, within the United States or any foreign jurisdiction in which we or any of our subsidiaries are then conducting clinical trials, providing services or products or marketing its services or products (or is engaged in active discussions to provide such services), that is engaged in the development, manufacture, marketing, distribution or sale of, or research directed to the development, manufacture, marketing, distribution or sale of, medical or aesthetic solutions or devices in the tattoo-removal or reduction of cellulite markets (a "Competing Business"), (iii) serving as an officer or director (or similar position) of a Competing Business, or (iv) requesting any person, firm or other entity that is a customer of the Company or any of its parents, subsidiaries, divisions or affiliates during Mr. Hauser's employment with us or during the 18-month period following the Closing to curtail or cancel such customer's business with us or any of our affiliates.

Off-balance Sheet Arrangements

As of September 30, 2021, 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.

Revenue and Related Selling Costs

Revenue Recognition

We derive our revenue from the sales of the RESONIC system, consisting of a console and handpiece, and, from time to time, related extended warranty arrangements, and from the sale of consumable cartridge cases, each of which includes our consumable cartridges and gel pads used by our customers during patient treatments. We earn revenue from the sale of these products to our customers. In accordance with the Financial Accounting Standards Board's ("FASB") Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606), we recognize revenue at the amount to which we expect to be entitled when control of the products or services is transferred to our customers. Control is generally transferred when we have a present right to payment and the title, and the significant risks and rewards of ownership of products or services are transferred to our customers. We recognize revenue when persuasive evidence of an arrangement exists, transfer of title to the customer has occurred, the sales price is fixed or determinable and collectability is reasonably assured. Revenue is deferred in the event that any of the revenue recognition criteria is not met. The sales of our RESONIC system generally includes hardware maintenance services for the first year, installation and training. In most cases, consoles are sold with hardware maintenance services with terms of approximately 12 months. The RESONIC console and cartridges contain enabling software that permits our customers to perform patient treatments. We do not market this software separately from the RESONIC console or from the consumable cartridges, rather, the functionality that the software provides is part of the overall RESONIC technology. We market the RESONIC system as a non-invasive aesthetic device for the improvement in the appearance of cellulite and for tattoo removal, not for its embedded software attributes included in the technology that enable its use. We do not provide rights to upgrades and enhancements or post contract customer support for the embedded software. Based on this assessment, we consider the embedded software in the RESONIC console and cartridges incidental to the RESONIC products as a whole and determined that revenue recognition should not be governed by the provisions of Topic 985 of the FASB Accounting Standards Codification, or ASC.

Persuasive Evidence of an Arrangement. We use contracts or customer purchase orders to determine the existence of an arrangement.

Delivery. Our standard terms specify that title transfers upon shipment to the customer. We use third party shipping notifications to verify that goods have shipped.

Sales Price Fixed or Determinable. We assess whether the sales price is fixed or determinable at the time of the transaction. Sales prices are documented in the executed sales contract or purchase order received prior to shipment. Our standard terms do not allow for trial or evaluation periods, rights of return or refund, payments contingent upon the customer obtaining financing or other terms that could impact the customer's obligation.

Collectability. We assess whether collection is reasonably assured based on a number of factors, including the customer's past transaction history and credit worthiness. With the customer's first order when we have no past transaction history, we collect a deposit before shipment and do not recognize income until we have certainty of receipt of the cash.

Significant Judgments

For contracts with multiple performance obligations, each of which represent promises within a contract that are distinct, we allocate revenue to all distinct performance obligations based on their relative stand-alone selling prices ("SSPs"). Our products and services included in our contracts with multiple performance obligations generally are not sold separately and there are no observable prices available to determine the SSP for those products and services. Since observable prices are not available, SSPs are established that reflect our best estimate of what the selling prices of the performance obligations would be if they were sold regularly on a stand-alone basis. Our process for estimating SSPs without observable prices considers multiple factors that may vary depending upon the unique facts and circumstances related to each performance obligation including, when applicable, the estimated cost to provide the performance obligation, market trends in the pricing for similar offerings, product-specific business objectives, and competitor or other relevant market pricing and margins. Because observable prices are generally not available for our performance obligations that are sold in bundled arrangements, we do not apply the residual approach to determining SSP. However, we do have certain performance obligations for which pricing is highly variable or uncertain, and contracts with those performance obligations generally contain multiple performance obligations with highly variable or uncertain pricing. For these contracts, we allocate the transaction price to those performance obligations using an

alternative method of allocation that is consistent with the allocation objective and the guidance on determining SSPs in Topic 606 considering, when applicable, the estimated cost to provide the performance obligation, market pricing for competing product or service offerings, residual values based on the estimated SSP for certain goods, product-specific business objectives, incremental values for bundled transactions that include a service relative to similar transactions that exclude the service, and competitor pricing and margins. A separate price has not been established by us for our hardware maintenance services. In addition, hardware maintenance services have not yet been sold separately and are proprietary in nature, and the related selling price of these services is highly variable or uncertain. Therefore, the SSP of these products and services is estimated using the alternative method described above, which includes residual value techniques.

Shipping and handling costs

We expense shipping and handling costs as incurred and include them in cost of revenue. In those cases where we bill shipping and handling costs to customers, we classify the amounts billed as revenue.

Sales tax

We exclude all taxes assessed by a governmental agency that are both imposed on and concurrent with the specific revenue-producing transaction from revenue (for example, sales and use taxes). In essence, we are reporting these amounts collected on behalf of the applicable government agency on a net basis as though they are acting as an agent. The taxes collected and not yet remitted to the governmental agency are included in accounts payable and accrued expenses in the accompanying balance sheets.

Customer Financing Arrangements

Through third-party leasing providers, our customers sometimes utilize financing programs that are designed to provide a leasing option whereby customers enter into purchase agreements with us and a separate financing or leasing contract with a third-party lender, who advances the proceeds from the sale to us upon contract execution and shipment of goods. The sales to the customer are final and we bear no risk of loss regarding subsequent payments.

Customer Programs and Payments

We regularly evaluate the adequacy of our estimates for customer incentive programs and pricing programs. Future market conditions and product transitions may require us to take action to change such programs. In addition, when the variables used to estimate these costs change, or if actual costs differ significantly from the estimates, we would be required to record incremental increases or reductions to sales, cost of goods sold or operating expenses.

Accruals for Customer Programs. We record an accrued liability for customer incentive programs. The estimated cost of these programs is recorded as a reduction of revenue or as an operating expense, if we receive a separately identifiable benefit from the customer and can reasonably estimate the fair value of that benefit. Significant management judgment and estimates must be used to determine the cost of these programs in any accounting period.

Customer Payments and Incentives

We enter into transactions where we provide consideration to our customers in the forms of cash payments in exchange for certain services provided under separate contractual arrangements. We account for such payments to customers in accordance with ASC 605-50, which requires management to characterize the payment as a reduction of revenue if we are unable to demonstrate the receipt of a benefit that is identifiable and sufficiently separable from the revenue transaction and reasonably estimate the fair value of the benefit identified. Significant management judgment and estimates must be used to determine the fair value of the benefit received in any period.

Product Warranties

Sales of our consoles and handpieces includes a limited 12-month warranty on product quality. We accrue warranty and related costs based on our best estimates when we determine that it is probable a charge or liability has been incurred and the amount of loss can be reasonably estimated. For new product introductions in which we may not have any historical experience, we make estimates for warranty claims based on a combination of historical experience of other similar products sold and qualitative and quantitative information. We exercise judgment in estimating the expected product warranty costs, using data such as the actual and projected product failure rates, estimated repair costs, material, labor, and overhead costs. Because we have no historical experience with which to provide a reliable basis for estimating such warranty cost, unforeseen quality issues

or component failure rates could result in future costs in excess of such estimates, or alternatively, improved quality and reliability in our products could result in actual expenses that are below those currently estimated.

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;
- costs to develop and defend our intellectual property; and
- costs related to compliance with regulatory requirements.

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, contract engineering and design activities, and other development costs. 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 as they are incurred. 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.

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 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, salaries, benefits and stock-based compensation for sales and marketing personnel, royalties and other miscellaneous expenses. As we commercialize, we expect our sales and marketing expenses to increase due to the anticipated growth of our business and related infrastructure as well as expanding our sales, marketing and support personnel. We recognize expenses to develop advertising materials as they are incurred.

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 for general and administrative personnel, insurance, travel costs and other administrative expenses and patent costs. Specifically, expenses related to the Merger are included in general and administrative expenses. We expect our general and administrative expenses to increase due to the Merger, the anticipated growth of our business and related infrastructure, as well as accounting, insurance, investor relations and other costs associated with being 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 five year life; computer equipment and software to have a three year life; furniture to have a three year life; and leasehold improvements to be depreciated over the shorter of the remaining lease term or useful lives of the asset.

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, research and development or sales and marketing expenses, depending upon the classification of the grantee. We estimate the fair value of options granted using the Black-Scholes option pricing 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.

Accounting for warrants

We issued warrants to purchase shares of common stock related to (i) bridge notes issued prior to our 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.

Related registration rights agreements for each private placement are accounted for in accordance with 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 historical volatility of comparable companies' stock. There are no expected dividends.

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, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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"), who serves as our principal executive officer, and Chief Financial Officer ("CFO"), who serves as our principal accounting officer, 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 September 30, 2021, of our disclosure controls and procedures. Based upon such evaluation and due to both the limited staffing of the Company at its early stage of development and the existence of the material weaknesses in our internal control over financial reporting described below, our CEO and CFO have concluded that, as of September 30, 2021, our disclosure controls and procedures were not effective.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As previously disclosed in our annual Report on Form 10-K for the year ended December 31, 2020, our management concluded that our internal control over financial reporting was, and continues to be, ineffective as of September 30, 2021 due to material weaknesses in our internal controls arising from a lack of segregation of duties, and the absence of internal staff with extensive knowledge of SEC financial and GAAP reporting. It should be noted that any system of controls, however well designed and operated, can provide only reasonable and not absolute assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of certain events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

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 and in August 2020, an experienced employee was hired in the accounting and finance department to focus on the further development of internal controls. Additionally, we hired one more experienced employee in the accounting and finance department in February of 2021 to further aid in the segregation of duties. In addition, we are retaining appropriate consultants to enhance our knowledge of SEC financial and GAAP reporting and upgrading our accounting system. In the fourth quarter of 2020, we began implementing a new ERP system to improve the previously reported limitations of our financial accounting system. Throughout the first quarter of 2021, we processed all accounting transactions in parallel in both our old and new financial reporting systems to ensure that our new system was properly functioning. In May 2021, we began to rely solely on the new financial reporting system which is capable of properly segregating duties within the system. Further improvement in our system of internal control over financial reporting has been slowed by the need to focus the attention of internal resources on the Merger and our commercial launch.

Furthermore, 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.

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.

As previously disclosed, on May 8, 2021, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with AbbVie Inc. (“AbbVie”) and Scout Merger Sub, Inc., a wholly owned subsidiary of AbbVie (“Merger Sub”), pursuant to which Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and a wholly owned subsidiary of AbbVie (the “Merger”). In connection with the Merger, the following complaints have been filed against us and the members of our board of directors: *Musanto v. Soliton, Inc., et al.*, Case No. 1:21-cv-05088 (S.D.N.Y. June 9, 2021); *Whitfield v. Soliton, Inc., et al.*, No. 1:21-cv-05330 (S.D.N.Y. June 16, 2021); *O’Guin v. Soliton, Inc., et al.*, No. 1:21-cv-05359 (S.D.N.Y. June 17, 2021); *Wiklund v. Soliton, Inc., et al.*, No. 1:21-cv-05386 (S.D.N.Y. June 18, 2021); *Boland v. Soliton, Inc., et al.*, No. 1:21-cv-05391 (S.D.N.Y. June 18, 2021); *Jabaloy v. Soliton, Inc., et al.*, No. 1:21-cv-03488 (E.D.N.Y. June 21, 2021); *Eder v. Soliton, Inc., et al.*, No. 1:21-cv-05474 (S.D.N.Y. June 22, 2021); *Post v. Soliton, Inc., et al.*, No. 1:21-cv-05496 (S.D.N.Y. June 23, 2021); *Ciccotelli v. Soliton, Inc., et al.*, No. 2:21-cv-02843 (E.D. Pa. June 25, 2021); *Walker v. Soliton, Inc., et al.*, No. 1:21-cv-00928 (D. Del. June 29, 2021); *Sheridan v. Soliton, Inc., et al.*, No. 1:21-cv-05656 (S.D.N.Y. June 30, 2021); *Siljanovski v. Soliton, Inc., et al.*, No. 1:21-cv-05935 (S.D.N.Y. July 9, 2021) (collectively, the “Complaints”). Each of the Complaints asserted claims under Sections 14(a) and 20(a) of the Exchange Act, and Rule 14a-9 promulgated thereunder, alleging that the Company’s Definitive Proxy Statement on Schedule 14A (the “Definitive Proxy Statement”) with respect to the special meeting of our stockholders held on July 20, 2021 omitted to disclose certain facts. In addition, the *Musanto* Complaint alleged that the named directors of the Company breached their fiduciary duties by approving the Merger Agreement through a flawed and unfair process and by failing to not make complete and accurate disclosures regarding this process and that we aided and abetted the alleged breaches. Each of the Complaints sought to enjoin or rescind the Merger and requests attorneys’ fees and damages in an unspecified amount. We also received a demand for books and records pursuant to Section 220 of the Delaware General Corporation Law. The demand sought books and records related to the Merger, the independence and disinterestedness of our board of directors and the Definitive Proxy Statement in order to investigate whether any wrongdoing or mismanagement took place in connection with the Merger. While we believe that the Complaints lacked merit and that the disclosures set forth in the Definitive Proxy Statement complied fully with applicable law, we determined to voluntarily supplement the Definitive Proxy Statement, as set forth in our Schedule 14A filed with the SEC on July 15, 2021, solely to avoid the expense, burden and risk associated with any litigation matter.

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 2020 Annual Report on Form 10-K and in our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2021 and June 30, 2021 (the “Q1 and Q2 2021 Quarterly Reports on Form 10-Q”), which are incorporated herein by reference. The risks described in the 2020 Annual Report on Form 10-K and in the Q1 and Q2 2021 Quarterly Reports on Form 10-Q are not the only risks facing us. 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. There have been no material changes to our risk factors from those set forth in our 2020 Annual Report on Form 10-K and in our Q1 and Q2 2021 Quarterly Reports on Form 10-Q, except as follows:

Supply chain issues, specifically related to shipping during the ongoing COVID-19 pandemic, have caused disruptions during our limited launch and could continue to cause disruptions in the future.

We have experienced delays in receipt of inventory due to delays among third-party transportation and shipping partners impacted by COVID-19. Staffing limitations in dock, transportation and warehouse partners have contributed to delayed deliveries both to our warehouse and to our customers from our warehouse. We expect this disruption to continue in the future until such labor shortages can be resolved.

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
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*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

(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
<u>/s/ Bradley Hauser</u> Bradley Hauser	Chief Executive Officer, President and Director (principal executive officer)	November 12, 2021
<u>/s/ Lori Bisson</u> Lori Bisson	Chief Financial Officer and Executive Vice-President (principal financial and accounting officer)	November 12, 2021

CERTIFICATION BY CHIEF EXECUTIVE OFFICER

I, Bradley Hauser, 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/ Bradley Hauser Bradley Hauser	Chief Executive Officer, President and Director (principal executive officer)	November 12, 2021

CERTIFICATION BY CHIEF FINANCIAL OFFICER

I, Lori Bisson, 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/ Lori Bisson Lori Bisson	Chief Financial Officer and Executive Vice-President (principal financial and accounting officer)	November 12, 2021

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 September 30, 2021 (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/ Bradley Hauser Bradley Hauser	Chief Executive Officer, President and Director (principal executive officer)	November 12, 2021

