

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

FORM 10-Q

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

For the quarterly period ended **March 31, 2020**

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: **001-35814**

Harrow Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

45-0567010

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

**102 Woodmont Blvd., Suite 610
Nashville, Tennessee**

(Address of principal executive offices)

37205

(Zip code)

(615) 733-4730

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a small reporting company, or an emerging growth company.

Large accelerated filer

Non-accelerated filer

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

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

Title of each class	Trading Symbol(s)	Name on exchange on which registered
Common Stock, \$0.001 par value per share	HROW	The NASDAQ Capital Market

As of May 8, 2020, there were 25,618,918 shares of the registrant's common stock, \$0.001 par value, outstanding.

HARROW HEALTH, INC.

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

HARROW HEALTH, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents, including restricted cash of \$200	\$ 4,124	\$ 4,949
Investment in Eton Pharmaceuticals	14,350	25,200
Accounts receivable, net	2,029	2,009
Inventories	3,989	3,301
Prepaid expenses and other current assets	1,316	1,308
Total current assets	25,808	36,767
Property, plant and equipment, net	5,147	5,375
Operating lease right-of-use assets	6,431	6,559
Intangible assets, net	2,345	2,337
Investment in Surface Pharmaceuticals	3,408	3,747
Investment in Melt Pharmaceuticals	3,422	3,968
Goodwill	332	332
TOTAL ASSETS	\$ 46,893	\$ 59,085
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 7,527	\$ 7,702
Accrued payroll and related liabilities	2,450	2,117
Deferred revenue and customer deposits	60	57
Current portion of note payable, net of unamortized debt discount	2,546	1,772
Current portion of operating lease obligations	634	629
Current portion of finance lease obligations	7	7
Total current liabilities	13,224	12,284
Operating lease obligations, net of current portion	6,212	6,338
Finance lease obligations, net of current portion	24	26
Accrued expenses, net of current portion	800	800
Note payable, net of current portion and unamortized debt discount	11,605	12,219
TOTAL LIABILITIES	31,865	31,667
COMMITMENTS AND CONTINGENCIES STOCKHOLDERS' EQUITY		
Common stock, \$0.001 par value, 50,000,000 shares authorized, 25,618,918 and 25,526,931 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	26	26
Additional paid-in capital	102,261	101,728
Accumulated deficit	(86,950)	(74,043)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY	15,337	27,711
Noncontrolling interests	(309)	(293)
TOTAL EQUITY	15,028	27,418
TOTAL LIABILITIES AND EQUITY	\$ 46,893	\$ 59,085

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

HARROW HEALTH, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except for share and per share data)

	For the Three Months Ended March 31, 2020	For the Three Months Ended March 31, 2019
Revenues:		
Sales, net	\$ 11,810	\$ 12,283
License revenues	7	7
Total revenues	11,817	12,290
Cost of sales	(3,626)	(3,898)
Gross profit	8,191	8,392
Operating expenses:		
Selling, general and administrative	8,416	8,543
Research and development	403	405
Total operating expenses	8,819	8,948
Loss from operations	(628)	(556)
Other income (expense):		
Interest expense, net	(560)	(603)
Investment (loss) gain from Melt Pharmaceuticals, net	(546)	5,525
Investment (loss) gain from Surface Pharmaceuticals, net	(339)	(243)
Investment (loss) gain from Eton Pharmaceuticals, net	(10,850)	6,580
Other income (expense), net	-	630
Total other (expense) income, net	(12,295)	11,889
(Loss) income before income taxes	(12,923)	11,333
Income tax benefit, net	-	-
Total net (loss) income including noncontrolling interests	(12,923)	11,333
Net loss attributable to noncontrolling interests	16	25
Net (loss) income attributable to Harrow Health, Inc.	\$ (12,907)	\$ 11,358
Basic net (loss) income per share of common stock	\$ (0.50)	\$ 0.46
Diluted net (loss) income per share of common stock	\$ (0.50)	\$ 0.43
Weighted average number of shares of common stock outstanding, basic	25,867,568	24,841,386
Weighted average number of shares of common stock outstanding, diluted	25,867,568	26,589,695

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

HARROW HEALTH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the three months ended March 31, 2020 and 2019
(In thousands, except for share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest	Total Stockholders' Equity
	Shares	Par Value					
Balance at December 31, 2018	24,339,610	\$ 24	\$ 98,938	\$ (74,211)	\$ 24,751	\$ -	\$ 24,751
Issuance of common stock in connection with:							
Exercise of warrants	364,039	1	161	-	162	-	162
Stock-based payment for services provided	15,000	-	75	-	75	-	75
Stock-based compensation expense	-	-	713	-	713	-	713
Net income	-	-	-	11,358	11,358	(25)	11,333
Balance at March 31, 2019	<u>24,718,649</u>	<u>\$ 25</u>	<u>\$ 99,887</u>	<u>\$ (62,853)</u>	<u>\$ 37,059</u>	<u>\$ (25)</u>	<u>\$ 37,034</u>
Balance at December 31, 2019	25,526,931	\$ 26	\$ 101,728	\$ (74,043)	\$ 27,711	\$ (293)	\$ 27,418
Issuance of common stock in connection with:							
Vesting of RSUs	91,987	-	-	-	-	-	-
Stock-based compensation expense	-	-	533	-	533	-	533
Net loss	-	-	-	(12,907)	(12,907)	(16)	(12,923)
Balance at March 31, 2020	<u>25,618,918</u>	<u>\$ 26</u>	<u>\$ 102,261</u>	<u>\$ (86,950)</u>	<u>\$ 15,337</u>	<u>\$ (309)</u>	<u>\$ 15,028</u>

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

HARROW HEALTH, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the Three Months Ended March 31, 2020	For the Three Months Ended March 31, 2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (loss) income (including noncontrolling interests)	\$ (12,923)	\$ 11,333
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization of property, plant and equipment	448	390
Amortization of intangible assets	45	62
Amortization of operating lease right-of-use assets	169	130
Amortization of debt issuance costs and discount	160	135
Investment loss (gain) from Eton, net	10,850	(6,580)
Investment loss (gain) from Surface, net	339	243
Investment loss (gain) from Melt, net	546	(5,525)
Gain on sale and disposal of assets	-	(4)
Stock-based payment of consulting services	-	75
Stock-based compensation	533	713
Changes in assets and liabilities:		
Accounts receivable	(20)	(280)
Inventories	(688)	(554)
Prepaid expenses and other current assets	(8)	(821)
Accounts payable and accrued expenses	(337)	158
Accrued payroll and related liabilities	333	(1,191)
Deferred revenue and customer deposits	3	240
NET CASH USED IN OPERATING ACTIVITIES	(550)	(1,476)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds on sale and disposal of assets	-	4
Investment in patent and trademark assets	(53)	(115)
Purchases of property, plant and equipment	(220)	(213)
NET CASH USED IN INVESTING ACTIVITIES	(273)	(324)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on finance lease obligations	(2)	(185)
Principal payments on note payable	-	(750)
Net proceeds from exercise of warrants	-	162
NET CASH USED IN FINANCING ACTIVITIES	(2)	(773)
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(825)	(2,573)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	4,949	6,838
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	\$ 4,124	\$ 4,265
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	\$ 3,924	\$ 4,065
Restricted cash	200	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	\$ 4,124	\$ 4,265
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	\$ -	\$ -
Cash paid for interest	\$ 408	\$ 467
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Right-of-use asset obtained in exchange for lease obligation	\$ 41	\$ -
Changes in accrued property and equipment purchases	\$ -	\$ 5
Acquisition of property, plant and equipment with finance lease obligations	\$ -	\$ 40

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

HARROW HEALTH, INC.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the three months ended March 31, 2020 and 2019
(Dollar amounts in thousands, except share and per share data)

NOTE 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Company and Background

Harrow Health, Inc. (together with its subsidiaries, partially owned companies and royalty arrangements unless the context indicates or otherwise requires, the “Company” or “Harrow”) specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace through its subsidiaries and deconsolidated companies. The Company owns one of the nation’s leading ophthalmology-focused pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, the Company also has equity positions in Eton Pharmaceuticals, Inc. (“Eton”), Surface Pharmaceuticals, Inc. (“Surface”), and Melt Pharmaceuticals, Inc. (“Melt”), all companies that began as subsidiaries of Harrow. More recently, the Company founded drug development subsidiaries Mayfield Pharmaceuticals, Inc. (“Mayfield”), Radley Pharmaceuticals, Inc. (“Radley”), and Stowe Pharmaceuticals, Inc. (“Stowe”). In 2020, Harrow created Visionology, Inc., which intends to launch an online eye health platform business. Harrow also owns royalty rights in various drug candidates being developed by Surface, Melt, Radley and Mayfield. The Company intends to continue to create, and hold equity and royalty rights in, new businesses that commercialize drug candidates that are internally developed or otherwise acquired or licensed from third parties.

Basis of Presentation

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and in accordance with the rules and regulations of the U.S. Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by GAAP for audited financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020 or for any other period. For further information, refer to the Company’s audited consolidated financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, as well as Mayfield, 79% majority controlled, and Stowe, 70% majority controlled, each subsidiaries of Harrow as of March 31, 2020. The remaining 21% of Mayfield is owned by Elle Pharmaceutical, LLC (“Elle”), TGV-Health, LLC and its affiliated entities (collectively “TGV”) or other consultants. Mayfield was organized to develop women’s health-focused drug candidates. The remaining 30% of Stowe is owned by TGV. Stowe was organized to develop ophthalmic drug candidates. All inter-company accounts and transactions have been eliminated in consolidation.

Harrow consolidates entities in which it has a controlling financial interest. We consolidate subsidiaries in which we hold and/or control, directly or indirectly, more than 50% of the voting rights. All intercompany accounts and transactions have been eliminated in consolidation.

The condensed consolidated balance sheets at March 31, 2020 and December 31, 2019 and the condensed consolidated statements of operations, stockholders’ equity and cash flows for the periods ended March 31, 2020 and 2019 include our accounts and those of our wholly owned subsidiaries as well as Mayfield and Stowe.

Risks, Uncertainties and Liquidity

The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. On March 18, 2020, the Centers for Medicare & Medicaid Services (“CMS”) released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. In addition to limiting elective medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendations, stay-at-home orders and other restrictive measures, and created significant volatility in financial markets.

Many of the Company’s customers use its drugs in procedures impacted by the CMS guidance to limit elective procedures. In addition, the Company and our business partners need access to healthcare providers and facilities to conduct clinical trials and other activities required to achieve regulatory clearance of products under development.

The Company believes reductions in elective procedures in response to CMS guidance have had, and will continue to have, an adverse impact, which may be material, to the Company’s financial condition, liquidity and results of operations. The severity of the impact of the COVID-19 pandemic on the Company’s business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on its customers, all of which are uncertain and cannot be predicted. As of the date of issuance of this Quarterly Report, the extent to which the COVID-19 pandemic may materially impact the Company’s financial condition, liquidity or results of operations is uncertain. For further information, refer to “Risk Factors” in Part II, Item 1A of this Quarterly Report.

The Company has incurred significant operating losses and negative cash flows from operations since its inception. The Company incurred operating losses of \$628 and \$556 for the three months ended March 31, 2020 and 2019, respectively, and had an accumulated deficit of \$86,950 and \$74,043 as of March 31, 2020 and December 31, 2019, respectively. In addition, the Company used cash in operating activities of \$550 and \$1,476 for the three months ended March 31, 2020 and 2019, respectively.

While there is no assurance, management of the Company believes existing cash resources and restricted cash of \$4,124 at March 31, 2020, along with \$2,967 in aggregate proceeds received from loan arrangements in April 2020 (see Note 16), will be sufficient to sustain the Company’s planned level of operations for at least the next twelve months. However, estimates of operating expenses and working capital requirements could be incorrect, and the Company could use its cash resources faster than anticipated. Further, some or all of the ongoing or planned activities may not be successful and could result in further losses.

The Company may seek to increase liquidity and capital resources through a variety of means which may include, but are not limited to: the sale of assets, investments and/or businesses, obtaining financing through the issuance of equity, debt, or convertible securities; and working to increase revenue growth through sales. There is no guarantee that the Company will be able to obtain capital when needed on terms management deems acceptable, or at all.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following represents an update for the three months ended March 31, 2020 to the significant accounting policies described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019.

Segments

The Company’s chief operating decision-maker is its Chief Executive Officer who makes resource allocation decisions and assesses performance based on financial information presented as operating segments. The Company has identified two operating segments as reportable segments. See Note 15 for more information regarding the Company’s reportable segments.

Noncontrolling Interests

The Company recognizes any noncontrolling interest as a separate line item in equity in the condensed consolidated financial statements. A noncontrolling interest represents the portion of equity ownership in a less-than-wholly owned subsidiary not attributable to the Company. Generally, any interest that holds less than 50% of the outstanding voting shares is deemed to be a noncontrolling interest; however, there are other factors, such as decision-making rights, that are considered as well. The Company includes the amount of net income (loss) attributable to noncontrolling interests in consolidated net income (loss) on the face of the condensed consolidated statements of operations.

The Company provides in the condensed consolidated statements of stockholders' equity a reconciliation at the beginning and the end of the period of the carrying amount of total equity, equity attributable to the parent, and equity attributable to the noncontrolling interests that separately discloses:

- (1) net income or loss;
- (2) transactions with owners acting in their capacity as owners, showing separately contributions from and distributions to owners; and
- (3) each component of other income or loss.

Basic and Diluted Net Income (Loss) per Common Share

Basic net income (loss) per common share is computed by dividing income (loss) attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted income (loss) per share is computed by dividing the income (loss) attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period.

Basic and diluted net income (loss) per share is computed using the weighted average number of shares of common stock outstanding during the period. Common stock equivalents (using the treasury stock or "if converted" method) from deferred acquisition obligations, stock options, unvested restricted stock units ("RSUs") and warrants were 5,253,638 and 5,838,230 at March 31, 2020 and 2019, respectively, and, except for the three months ended March 31, 2019, are excluded from the calculation of diluted net income (loss) per share for the periods presented, because the effect is anti-dilutive. Included in the basic and diluted net income (loss) per share calculation were RSUs awarded to directors that had vested, but the issuance and delivery of the shares are deferred until the director resigns. The number of shares underlying vested RSUs at March 31, 2020 and 2019 was 244,460 and 270,783, respectively.

The following table shows the computation of basic net income (loss) per share of common stock for the three months ended March 31, 2020 and 2019:

	For the Three Months Ended March 31,	
	2020	2019
Numerator – net (loss) income attributable to Harrow Health, Inc.	\$ (12,907)	\$ 11,358
Denominator – weighted average number of shares outstanding, basic	25,867,568	24,841,386
Net (loss) income per share, basic	\$ (0.50)	\$ 0.46

For the three months ended March 31, 2019, the Company had net income. As a result, the Company computed diluted net income per share using the weighted-average number of common shares and dilutive common equivalent shares outstanding during those periods. Diluted common equivalent shares for the three months ended March 31, 2019, consisted of the following:

	March 31, 2019
Diluted shares related to:	
Warrants	1,067,808
Stock options	680,501
Dilutive common equivalent shares	<u>1,748,309</u>

The following table shows the computation of diluted net income (loss) per share of common stock for the three months ended March 31, 2020 and 2019:

	For the Three Months Ended March 31,	
	2020	2019
Numerator – net (loss) income attributable to Harrow Health, Inc.	\$ (12,907)	\$ 11,358
Denominator – weighted average number of shares outstanding, basic	25,867,568	24,841,386
Dilutive common equivalent shares	-	1,748,309
Number of shares used for diluted earnings per share computation	<u>25,867,568</u>	<u>26,589,695</u>
Net (loss) income per share, diluted	<u>\$ (0.50)</u>	<u>\$ 0.43</u>

Investment in Eton Pharmaceuticals, Inc. – Related Party

The Company owns 3,500,000 shares of Eton common stock, which represents approximately 16.9% of the equity and voting interests of Eton as of March 31, 2020. At March 31, 2020, the last trading day of the period ended March 31, 2020, the fair market value of Eton's common stock was \$4.10 per share. In accordance with the Accounting Standards Update ("ASU") 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, the Company recorded an unrealized investment loss from its Eton common stock position of \$10,850 and an unrealized investment gain of \$6,580 during the three months ended March 31, 2020 and 2019, respectively, related to the change in fair market value of the Company's investment in Eton during the measurement period. As of March 31, 2020, the fair market value of the Company's investment in Eton was \$14,350.

Mark Baum, the Company's Chief Executive Officer, is a member of the board of directors of Eton.

Investment in Melt Pharmaceuticals, Inc. – Related Party

In April 2018, the Company formed Melt as a wholly owned subsidiary. In January and March of 2019, Melt entered into definitive stock purchase agreements (collectively, the "Melt Series A Preferred Stock Agreement") with certain investors and closed on the purchase and sale of Melt's Series A Preferred Stock (the "Melt Series A Stock"), totaling approximately \$11,400 of proceeds (collectively the "Melt Series A Round") at a purchase price of \$5.00 per share. As a result, the Company lost voting and ownership control of Melt and ceased consolidating Melt's financial statements.

In January 2019, the Company deconsolidated Melt and recorded a gain of \$5,810 and adjusted the carrying value in Melt to reflect the increased valuation of Melt and the Company's new ownership interest in accordance with Accounting Standard Codification ("ASC") 810-10-40-4(c), *Consolidation*.

The Company owns 3,500,000 common shares (which is approximately 44% of the equity interests as of March 31, 2020) of Melt and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Melt. Under this method, the Company recognizes earnings and losses in Melt in its condensed consolidated financial statements and adjusts the carrying amount of its investment in Melt accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Melt. Any intra-entity profits and losses are eliminated. During the three months ended March 31, 2020 and 2019, the Company recorded equity in the net losses of Melt of \$546 and \$285, respectively. As of March 31, 2020, the carrying value of the Company's investment in Melt was \$3,422.

See Note 4 for more information and related party disclosure regarding Melt.

Investment in Surface Pharmaceuticals, Inc. – Related Party

The Company owns 3,500,000 common shares (which is approximately 30% of the equity interests as of March 31, 2020) of Surface and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, the Company recognizes earnings and losses in Surface in its condensed consolidated financial statements and adjusts the carrying amount of its investment in Surface accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Surface. Any intra-entity profits and losses are eliminated. The Company recorded equity in the net losses of Surface of \$339 and \$243 during the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, the carrying value of the Company's investment in Surface was \$3,408.

See Note 5 for more information and related party disclosure regarding Surface.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with a forward-looking expected credit loss model which will result in earlier recognition of credit losses. The Company adopted ASU 2016-13 on January 1, 2020, and adoption of the standard did not have a material effect on the Company's consolidated financial position, results of operations and cash flows.

In August 2018, the FASB issued ASU 2018-13, *Changes to Disclosure Requirements for Fair Value Measurements*, which improved the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements. The Company adopted ASU 2018-13 on January 1, 2020, and adoption of the standard did not have a material effect on the Company's consolidated financial position, results of operations and cash flows.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other*. This guidance simplifies the accounting for goodwill impairment for all entities by requiring impairment charges to be based on the first step in the current two-step impairment test under ASC 350. The updated standard eliminates the requirement to calculate a goodwill impairment charge using Step 2. If a reporting unit's carrying amount exceeds its fair value, an entity will record an impairment charge based on that difference. The impairment charge will be limited to the amount of goodwill allocated to that reporting unit. ASU 2017-04 is effective for reporting periods beginning after December 31, 2019 on a prospective basis, and early adoption is permitted. The Company adopted ASU 2017-04 on January 1, 2020, and adoption of the standard did not have a material effect on the Company's consolidated financial position, results of operations and cash flows.

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in accounting standards. The amendments in the ASU are effective for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption of the standard is permitted. The Company does not expect ASU 2019-12 to have a material impact on its consolidated financial position, results of operations and cash flows.

NOTE 3. REVENUES

The Company accounts for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers*. The Company has two primary streams of revenues: (1) revenues recognized from our sale of products within our pharmacy services and (2) revenues recognized from intellectual property license and asset purchase agreements.

Product Revenues from Pharmacy Services

The Company sells prescription drugs directly through our pharmacy and outsourcing facility network. Revenues from our pharmacy services division includes: (i) the portion of the price the client pays directly to us, net of any volume-related or other discounts paid back to the client, (ii) the price paid to us by individuals, and (iii) customer copayments made directly to the pharmacy network. Sales taxes are not included in revenue. Following the core principle of ASC 606, we have identified the following:

1. Identify the contract(s) with a customer: A contract exists with a customer at the time the prescription or order is received by the Company.
2. Identify the performance obligations in the contract: The order received contains the performance obligations to be met, in almost all cases the product the customer is wishing to receive. If we are unable to be meet the performance obligation, the customer is notified.
3. Determine the transaction price: the transaction price is based on the product being sold to the customer, and any related customer discounts. These amounts are pre-determined and built into our order management software.
4. Allocate the transaction price to the performance obligations in the contract: The transaction price associated with the product(s) being ordered is allocated according to the pre-determined amounts.
5. Recognize revenue when (or as) the entity satisfies a performance obligation: At the time of shipment from the pharmacy or outsourcing facility, the performance obligation has been met.

The following revenue recognition policy has been established for the pharmacy services division:

Revenues generated from prescription or office use drugs sold by our pharmacies and outsourcing facility are recognized when the prescription is shipped. At the time of shipment, the pharmacy services division has performed substantially all of its obligations under its client contracts and does not experience a significant level of returns or reshipments. Determination of criteria (3) and (4) is based on management's judgments regarding the fixed nature of the selling prices of the products delivered and the collectability of those amounts. The Company records reductions to revenue for discounts at the time of the initial sale. Estimated returns and allowances and other adjustments are provided for in the same period during which the related sales are recorded and are based on actual returns history. The rate of returns is analyzed annually to determine historical returns experience. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. The Company will defer any revenues received for a product that has not been delivered or is subject to refund until such time that the Company and the customer jointly determine that the product has been delivered and no refund will be required.

Intellectual Property License Revenues

The Company currently holds five intellectual property license and related agreements in which the Company has promised to grant a license or sale which provides a customer with the right to access the Company's intellectual property. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive license rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements can be multiple-element arrangements, the revenue of which is recognized at the point of time the performance obligation is met.

Non-refundable fees that are not contingent on any future performance by the Company and require no consequential continuing involvement on the part of the Company are recognized as revenue when the license term commences and the licensed data, technology, compounded drug preparation and/or other deliverable is delivered. Such deliverables may include physical quantities of compounded drug preparations, design of the compounded drug preparations and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patent applications for such compounded drug preparations. The Company defers recognition of non-refundable fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee and that are separate and independent of the Company's performance under the other elements of the arrangement. In addition, if the Company's continued involvement is required, through research and development services that are related to its proprietary know-how and expertise of the delivered technology or can only be performed by the Company, then such non-refundable fees are deferred and recognized over the period of continuing involvement. Guaranteed minimum annual royalties are recognized on a straight-line basis over the applicable term.

Revenue disaggregated by revenue source for the three months ended March 31, 2020 and 2019, consists of the following:

	For the Three Months Ended March 31,	
	2020	2019
Product sales, net	\$ 11,810	\$ 12,283
License revenues	7	7
Total revenues	\$ 11,817	\$ 12,290

Deferred revenue and customer deposits at March 31, 2020 and December 31, 2019, was \$60 and \$57, respectively. All deferred revenue and customer deposit amounts at December 31, 2019 were recognized as revenue during the three months ended March 31, 2020.

NOTE 4. INVESTMENT IN MELT PHARMACEUTICALS, INC. AND AGREEMENTS - RELATED PARTY TRANSACTIONS

In December 2018, the Company entered into an asset purchase agreement with Melt (the “Melt Asset Purchase Agreement”). Pursuant to the terms of the Melt Asset Purchase Agreement, Melt was assigned certain intellectual property and related rights from the Company to develop, formulate, make, sell, and sub-license certain Company conscious sedation and analgesia related formulations (collectively, the “Melt Products”). Under the terms of the Melt Asset Purchase Agreement, Melt is required to make royalty payments to the Company up to 5% of net sales of the Melt Products while any patent rights remain outstanding, as well as other conditions. In January and March 2019, the Company entered into the Melt Series A Preferred Stock Agreement.

In February 2019, the Company and Melt entered into a Management Services Agreement (the “Melt MSA”), whereby the Company provides to Melt certain administrative services and support, including bookkeeping, web services and human resources related activities, and Melt pays the Company a monthly amount of \$10.

As of March 31, 2020, the Company was due \$754 from Melt for reimbursable expenses and amounts due under the Melt MSA and are included in prepaid expenses and other current assets on the accompanying condensed consolidated balance sheets. During the three months ended March 31, 2020, Melt paid the Company \$0.

The Company’s Chief Executive Officer, Mark L. Baum, and Chief Medical Officer, Larry Dillaha, are members of the Melt board of directors.

The unaudited condensed results of operations information of Melt is summarized below:

	For the Three Months Ended March 31, 2020	
Revenues, net	\$	-
Loss from operations		1,235
Net loss	\$	(1,235)

The unaudited condensed balance sheet information of Melt is summarized below:

	March 31, 2020	
Current assets	\$	6,148
Non current assets		12
Total assets	\$	6,160
Total liabilities	\$	1,598
Total preferred stock and stockholders’ equity		4,562
Total liabilities and stockholders’ equity	\$	6,160

NOTE 5. INVESTMENT IN SURFACE PHARMACEUTICALS, INC. AND AGREEMENTS - RELATED PARTY TRANSACTIONS

The Company entered into an asset purchase and license agreement in 2017, and amended it in April 2018 (the “Surface License Agreements”) with Surface. Pursuant to the terms of the Surface License Agreements, the Company assigned and licensed to Surface certain intellectual property and related rights to develop, formulate, make, sell, and sub-license ophthalmic formulations (collectively, the “Surface Products”). Surface is required to make royalty payments to the Company of 4%-6% of net sales of the Surface Products while any patent rights remain outstanding.

As of March 31, 2020, the Company owned 3,500,000 shares of Surface common stock (approximately 30% of the issued and outstanding equity interests). A Company director, Richard L. Lindstrom, and the Company’s Chief Executive Officer, Mark L. Baum, are directors of Surface. Surface is required to make royalty payments to Dr. Lindstrom of 3% of net sales of certain Surface products while certain patent rights remain outstanding. Dr. Lindstrom is also a principal of Flying L Partners, an affiliate of the funding investor who purchased the Surface Series A Preferred Stock.

The unaudited condensed results of operations information of Surface is summarized below:

	For the Three Months Ended March 31, 2020
Revenues, net	\$ -
Loss from operations	1,131
Net loss	<u>\$ (1,131)</u>

The unaudited condensed balance sheet information of Surface is summarized below:

	March 31, 2020
Current assets	\$ 14,578
Non current assets	47
Total assets	<u>\$ 14,625</u>
Total liabilities	\$ 348
Total stockholders’ equity	14,277
Total liabilities and stockholders’ equity	<u>\$ 14,625</u>

NOTE 6. INVENTORIES

Inventories are comprised of finished compounded formulations, over-the-counter and prescription retail pharmacy products, commercial pharmaceutical products, related laboratory supplies and active pharmaceutical ingredients. The composition of inventories as of March 31, 2020 and December 31, 2019 was as follows:

	March 31, 2020	December 31, 2019
Raw materials	\$ 3,033	\$ 2,405
Work in progress	7	20
Finished goods	949	876
Total inventories	<u>\$ 3,989</u>	<u>\$ 3,301</u>

NOTE 7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	March 31, 2020	December 31, 2019
Prepaid insurance	\$ 133	\$ 123
Other prepaid expenses	340	358
Receivable due from Melt	754	722
Deposits and other current assets	89	105
Total prepaid expenses and other current assets	\$ 1,316	\$ 1,308

NOTE 8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net consisted of the following:

	March 31, 2020	December 31, 2019
Property, plant and equipment, net:		
Computer software and hardware	\$ 1,758	\$ 1,732
Furniture and equipment	437	363
Lab and pharmacy equipment	3,179	3,164
Leasehold improvements	5,616	5,510
	10,990	10,769
Accumulated depreciation and amortization	(5,843)	(5,394)
	\$ 5,147	\$ 5,375

For the three months ended March 31, 2020 and 2019, depreciation and amortization related to the property, plant and equipment was \$448 and \$390, respectively.

NOTE 9. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at March 31, 2020 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Impairment	Net Carrying value
Patents	17-19 years	\$ 862	\$ (72)	\$ -	\$ 790
Licenses	20 years	50	(6)	-	44
Trademarks	Indefinite	344	-	-	344
Customer relationships	3-15 years	1,519	(353)	-	1,166
Trade name	5 years	5	(5)	-	-
Non-competition clause	3-4 years	50	(50)	-	-
State pharmacy licenses	25 years	8	(7)	-	1
		<u>\$ 2,838</u>	<u>\$ (493)</u>	<u>\$ -</u>	<u>\$ 2,345</u>

Amortization expense for intangible assets for the three months ended March 31, 2020 and 2019 was as follows:

	For the Three Months Ended March 31, 2020	For the Three Months Ended March 31, 2019
Patents	\$ 11	\$ 4
Licenses	1	4
Customer relationships	33	51
Trade name	-	2
State pharmacy licenses	-	1
	<u>\$ 45</u>	<u>\$ 62</u>

Estimated future amortization expense for the Company's intangible assets at March 31, 2020 is as follows:

Remainder of 2020	\$ 145
2021	104
2022	104
2023	104
2024	104
Thereafter	1,440
	<u>\$ 2,001</u>

NOTE 10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	March 31, 2020	December 31, 2019
Accounts payable	\$ 7,300	\$ 7,409
Other accrued expenses	49	49
Accrued interest	178	244
Accrued exit fee for note payable	800	800
Total accounts payable and accrued expenses	<u>8,327</u>	<u>8,502</u>
Less: Current portion	(7,527)	(7,702)
Non-current total accrued expenses	<u>\$ 800</u>	<u>\$ 800</u>

NOTE 11. DEBT

In July 2017, the Company entered into a term loan and security agreement in the principal amount of \$16,000 (the “SWK Loan Agreement” or “SWK Loan”) with SWK Funding LLC and its partners (collectively, “SWK”), as lender and collateral agent. The SWK Loan Agreement was fully funded at closing with a five-year term; however, such term could be reduced to four years if certain revenue requirements are not achieved. The SWK Loan is secured by substantially all of the Company’s assets, including its intellectual property rights. The SWK Loan was subsequently amended in May 2019 and again in April 2020 (see Note 16). The SWK Loan bears an interest rate that is equal to the three-month London Inter-Bank Offered Rate (subject to a minimum of 2.00%), plus an applicable margin of 10.00% (the “Margin Rate”); provided that, if, two days prior to a payment date, the Company provides SWK evidence that the Company has achieved a leverage ratio as of such date of less than 4.00:1:00, the Margin Rate shall equal 9.00%; and if the Company has achieved a leverage ratio as of such date of less than 3.00:1:00, the Margin Rate shall equal 7.00%. The leverage ratio means, as of any date of determination, the ratio of: (a) indebtedness as of such date to (b) EBITDA (as defined in the SWK Loan), of the Company for the immediately preceding 12 month period, adding-back (i) actual litigation expenses for the immediately preceding 12 month period, minus (ii) actual litigation expenses for the immediately preceding 3 month period multiplied by 4.

At March 31, 2020, future minimum payments under the Company’s note payable were as follows:

	Amount
Remainder of 2020	\$ 3,288
2021	4,121
2022	3,828
2023	7,506
Total minimum payments	18,743
Less: amount representing estimated interest	(3,493)
Notes payable, gross	15,250
Less: unamortized discount	(1,099)
	14,151
Less: current portion, net of unamortized discount	(2,546)
Note payable, net of current portion and unamortized debt discount	\$ 11,605

For the three months ended March 31, 2020, debt discount amortization related to the note payable was \$160.

NOTE 12. LEASES

The Company adopted Topic 842 on January 1, 2019. Topic 842 allows the Company to elect a package of practical expedients, which include: (i) an entity need not reassess whether any expired or existing contracts are or contain leases; (ii) an entity need not reassess the lease classification for any expired or existing leases; and (iii) an entity need not reassess any initial direct costs for any existing leases. Another practical expedient allows the Company to use hindsight in determining the lease term when considering lessee options to extend or terminate the lease and to purchase the underlying asset. The Company has elected to utilize the package of practical expedients and has not elected the hindsight methodology in its implementation of Topic 842.

The Company elected to adopt this standard using the optional modified retrospective transition method and recognized a cumulative-effect adjustment to the condensed consolidated balance sheet on the date of adoption. Comparative periods have not been restated. With the adoption of Topic 842, the Company’s condensed consolidated balance sheets now contains the following line items: Right-of-use assets, Operating lease liabilities—short-term and Operating lease liabilities—long-term.

The Company determined that it held the following significant operating leases of office and laboratory space as of January 1, 2019:

- An operating lease for 10,200 square feet of office space in San Diego, California that expires in December 2021, with an option to extend the term for a five-year period;
- An operating lease for 4,500 square feet of office and lab space in Irvine, California that expires in December 2020, with an option to extend the term for up to two five-year periods. As part of the Company's restructuring of the Park Compounding, Inc. ("Park") business, the Company assessed its obligations under this lease. As of the date of this Quarterly Report, the Company expects to sublease this space and has determined that there is a practical ability to do so, and as a result did not recognize any impairment costs related to this lease and the Company's right to use asset;
- An operating lease for 25,000 square feet of lab, warehouse and office space in Ledgewood, New Jersey that expires in July 2024, with an option to extend the term for two additional five-year periods; and
- An operating lease for 5,500 square feet of office space in Nashville, Tennessee that expires in December 2024, with an option to extend the term for two additional five-year periods.

The extensions within the San Diego, California and Ledgewood, New Jersey operating lease agreements were included within the Company's calculation of the new lease standard as the Company is reasonably certain it will exercise its option to extend these leases. The Company has elected to not recognize right-of-use assets and lease liabilities arising from short-term leases, which are leases that, at the commencement date, have a lease term of 12 months or less and do not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

The previously classified capital leases are now classified as finance leases under the new standard. The Company has determined that the identified finance leases did not contain non-lease components and require no further allocation of the total lease cost. The Company has determined that the identified operating leases did contain non-lease components and elected an accounting policy to combine non-lease and lease components to determine the total lease cost. Additionally, the operating agreements in place did not contain information to determine the rate implicit in the leases. As such, the Company calculated the incremental borrowing rate based on the assumed remaining lease term for each lease in order to calculate the present value of the remaining lease payments. At March 31, 2020, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 6.32% and 10.01 years, respectively.

Upon adoption of Topic 842, the Company recorded a \$6,325 increase in operating lease right-of-use assets, a \$388 decrease in accounts payable and accrued expenses and a \$6,712 increase in operating lease liability. The Company did not record any cumulative effect adjustments to opening stockholders' equity. As of March 31, 2020, right-of-use assets and liabilities arising from operating leases were \$6,431 and \$6,846, respectively. During the three months ended March 31, 2020 and 2019, cash paid for amounts included for the operating lease liabilities was \$271 and \$223 and the Company recorded operating lease expense of \$278 and \$234 included in selling, general and administrative expenses, respectively.

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

	Operating Leases
Remainder of 2020	\$ 831
2021	987
2022	1,008
2023	1,032
2024	1,035
Thereafter	4,465
Total minimum lease payments	9,358
Less: amount representing interest payments	(2,512)
Total operating lease liabilities	6,846
Less: current portion, operating lease liabilities	(634)
Operating lease liabilities, net of current portion	\$ 6,212

The Company also has an additional finance lease that is included in its lease accounting but is not considered significant.

Future lease payments under non-cancelable finance leases as of March 31, 2020 were as follows:

	Finance Leases
Remainder of 2020	\$ 7
2021	9
2022	9
2023	9
2024	1
Total minimum lease payments	<u>35</u>
Less: amount representing interest payments	<u>(4)</u>
Present value of future minimum lease payments	31
Less: current portion, finance lease obligation	<u>(7)</u>
Finance lease obligation, net of current portion	<u>\$ 24</u>

At March 31, 2020, the weighted average incremental borrowing rate and the weighted average remaining lease term for the finance lease held by the Company were 6.36% and 3.83 years, respectively.

For the three months ended March 31, 2020, depreciation expense related to the equipment held under the finance lease obligation was \$2.

For the three months ended March 31, 2020, cash paid and expense recognized for interest expense related to the finance lease obligation was \$1.

NOTE 13. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Common Stock

In February 2020, the Company accrued for the issuance of 15,000 shares of its restricted common stock, with a fair value of \$83, as consideration for commission expenses incurred during the three months ended March 31, 2020. Issuance of these shares had not occurred as of March 31, 2020.

During the three months ended March 31, 2020, the Company issued 91,987 shares of its common stock underlying RSUs issued to a director that resigned. The RSUs had previously vested, including 2,429 RSUs during the three months ended March 31, 2020, but the issuance and delivery of the shares were deferred until the director resigned.

During the three months ended March 31, 2020, 9,715 shares of the Company's common stock underlying RSUs issued to directors vested, but the issuance and delivery of these shares are deferred until the director resigns.

Stock Option Plan

On September 17, 2007, the Company's Board of Directors and stockholders adopted the Company's 2007 Incentive Stock and Awards Plan, which was subsequently amended on November 5, 2008, February 26, 2012, July 18, 2012, May 2, 2013 and September 27, 2013 (as amended, the "2007 Plan"). The 2007 Plan reached its term in September 2017, and we can no longer issue additional awards under this plan, however, options previously issued under the 2007 Plan will remain outstanding until they are exercised, reach their maturity or are otherwise cancelled/forfeited. On June 13, 2017, the Company's Board of Directors and stockholders adopted the Company's 2017 Incentive Stock and Awards Plan (the "2017 Plan" together with the 2007 Plan, the "Plans"). As of March 31, 2020, the 2017 Plan provides for the issuance of a maximum of 2,000,000 shares of the Company's common stock. The purpose of the Plans are to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in the Company's development and financial success. Under the Plans, the Company is authorized to issue incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-qualified stock options, restricted stock units and restricted stock. The Plans are administered by the Compensation Committee of the Company's Board of Directors. The Company had 585,406 shares available for future issuances under the 2017 Plan at March 31, 2020.

Stock Options

A summary of stock option activity under the Plans for the three months ended March 31, 2020 is as follows:

	<u>Number of shares</u>	<u>Weighted Avg. Exercise Price</u>	<u>Weighted Avg. Remaining Contractual Life</u>	<u>Aggregate Intrinsic Value</u>
Options outstanding - January 1, 2020	2,656,683	\$ 5.31		
Options granted	299,500	\$ 6.98		
Options exercised	-	\$ -		
Options cancelled/forfeited	(3,717)	\$ 2.61		
Options outstanding - March 31, 2020	<u>2,952,466</u>	\$ 5.49	5.30	\$ 1,394
Options exercisable	<u>1,691,501</u>	\$ 4.52	5.59	\$ 1,162
Options vested and expected to vest	<u>2,833,869</u>	\$ 5.42	5.32	\$ 1,387

The aggregate intrinsic value in the table above represents the total pre-tax amount of the proceeds, net of exercise price, which would have been received by option holders if all option holders had exercised and immediately sold all options with an exercise price lower than the market price on March 31, 2020, based on the closing price of the Company's common stock of \$3.82 on that date.

During the three months ended March 31, 2020, the Company granted stock options to certain employees and a consultant. The stock options were granted with an exercise price equal to the current market price of the Company's common stock, as reported by the securities exchange on which the common stock was then listed, at the grant date and have contractual terms of 10 years. Vesting terms for options granted to employees and consultants during the three months ended March 31, 2020 typically included one of the following vesting schedules: 25% of the shares subject to the option vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the shares subject to the option vest and become exercisable quarterly in equal installments thereafter over three years; and 100% of the shares subject to the option vest on a quarterly basis in equal installments over three years. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plan) and in the event of certain modifications to the option award agreement.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model. The expected term of options granted to employees and directors was determined in accordance with the “simplified approach,” as the Company has limited, relevant, historical data on employee exercises and post-vesting employment termination behavior. The expected risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates. For option grants to employees and directors, the Company assigns a forfeiture rate of 10%. These factors could change in the future, which would affect the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant.

The table below illustrates the fair value per share determined by the Black-Scholes-Merton option pricing model with the following assumptions used for valuing options granted to employees:

	2020
Weighted-average fair value of options granted	\$ 4.78
Expected terms (in years)	5.8 - 6.1
Expected volatility	66% - 67%
Risk-free interest rate	1.32% - 1.64%
Dividend yield	-

The following table summarizes information about stock options outstanding and exercisable at March 31, 2020:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ 1.47 - \$2.60	780,190	6.41	\$ 2.05	671,164	\$ 2.09	
\$ 2.76 - \$4.66	481,655	6.05	\$ 3.94	446,211	\$ 3.97	
\$ 5.49 - \$6.36	440,350	7.66	\$ 6.15	208,355	\$ 6.10	
\$ 6.64 - \$8.99	1,245,241	3.51	\$ 7.85	360,741	\$ 8.24	
\$ 42.80	5,030	0.37	\$ 42.80	5,030	\$ 42.80	
\$ 1.47 - \$42.80	<u>2,952,466</u>	5.30	\$ 5.49	<u>1,691,501</u>	\$ 4.52	

As of March 31, 2020, there was approximately \$4,887 of total unrecognized compensation expense related to unvested stock options granted under the Plans. That expense is expected to be recognized over the weighted-average remaining vesting period of 1.75 years. The stock-based compensation expense for all stock options was \$263 during the three months ended March 31, 2020.

Restricted Stock Units

RSU awards are granted subject to certain vesting requirements and other restrictions, including performance and market-based vesting criteria. The grant date fair value of the RSUs, which has been determined based upon the market value of the Company’s common stock on the grant date, is expensed over the vesting period of the RSUs. Unvested portions of RSUs issued to consultants are remeasured on an interim basis until vesting criteria is met.

During the three months ended March 31, 2020, 111,000 RSUs with a fair market value of \$810 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.

During the three months ended March 31, 2020, the Company granted 10,000 RSUs to a new member of its board of directors, with a fair market value of \$39 which vests on the one year anniversary of date granted.

A summary of the Company's RSU activity and related information for the three months ended March 31, 2020 is as follows:

	<u>Number of RSUs</u>	<u>Weighted Average Grant Date Fair Value</u>
RSUs unvested - January 1, 2020	1,411,930	\$ 2.76
RSUs granted	121,000	\$ 7.02
RSUs vested	(12,144)	\$ 7.72
RSUs cancelled/forfeited	-	
RSUs unvested at March 31, 2020	<u>1,520,786</u>	<u>\$ 3.06</u>

As of March 31, 2020, the total unrecognized compensation expense related to unvested RSUs was approximately \$1,621, which is expected to be recognized over a weighted-average period of 0.5 years, based on estimated and actual vesting schedules of the applicable RSUs. The stock-based compensation for RSUs during the three months ended March 31, 2020 and 2019 was \$259 and \$709, respectively.

Warrants

From time to time, the Company issues warrants to purchase shares of the Company's common stock to investors, lenders, underwriters and other non-employees for services rendered or to be rendered in the future, or pursuant to settlement agreements.

A summary of warrant activity for the three months ended March 31, 2020 is as follows:

	<u>Number of Shares Subject to Warrants Outstanding</u>	<u>Weighted Avg. Exercise Price</u>
Warrants outstanding - January 1, 2020	780,386	\$ 2.12
Granted	-	
Exercised	-	-
Expired	-	
Warrants outstanding and exercisable - March 31, 2020	<u>780,386</u>	<u>\$ 2.12</u>
Weighted average remaining contractual life of the outstanding warrants in years - March 31, 2020	<u>4.28</u>	

Warrants outstanding and exercisable as of March 31, 2020 are as follows:

<u>Warrant Series</u>	<u>Issue Date</u>	<u>Warrants Outstanding</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
Lender warrants	5/11/2015	125,000	\$ 1.79	5/11/2025
Settlement warrants	8/16/2016	40,000	\$ 3.75	8/16/2021
Lender warrants	7/19/2017	615,386	\$ 2.08	7/19/2024
		<u>780,386</u>	<u>\$ 2.12</u>	

Subsidiary Stock-Based Transactions

Mayfield Pharmaceuticals, Inc.

During the three months ended March 31, 2020, Mayfield re-purchased 650,000 shares of its common stock from Elle, for an aggregate purchase price of \$1.

During the three months ended March 31, 2020, Mayfield issued 475,000 shares of its restricted common stock that vest upon various performance-based milestones and service periods to consultants of Mayfield, including Mayfield's CEO candidate.

During the three months ended March 31, 2020, 500,000 shares of Mayfield's restricted common stock were forfeited by a consultant.

Stock-Based Compensation Summary

The Company recorded stock-based compensation related to equity instruments granted to employees, directors and consultants as follows:

	For the Three Months Ended March	
	31	
	2020	2019
Employees - selling, general and administrative	\$ 436	\$ 638
Directors - selling, general and administrative	97	75
Consultants - selling, general and administrative	-	75
Total	\$ 533	\$ 788

NOTE 14. COMMITMENTS AND CONTINGENCIES

Novel Drug Solutions et al.

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA (collectively "NDS") filed a lawsuit against the Company in the U.S. District Court of Delaware asserting claims for breach of contract. The claims stem from an asset purchase agreement between the Company and NDS entered into in 2013. In July 2019, NDS filed a second amended complaint which added a claim related to its purported termination of the APA. In October 2019, NDS voluntarily dismissed all claims related to breach of contract, leaving only claims related to the scope of the post-termination obligations to be litigated. NDS is seeking unspecified damages, interest, attorney's fees and other costs. The Company believes the claims are meritless and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend against these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation and it could result in substantial costs, losses and a diversion of management's resources and attention, which could harm the Company's business and the value of its common stock.

Product and Professional Liability

Product and professional liability litigation represents an inherent risk to all firms in the pharmaceutical and pharmacy industry. We utilize traditional third-party insurance policies with regard to our product and professional liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

In January 2018, John Erick and Deborah Ferrell, successors-in-interest and heirs of Jade Erick, (collectively “Erick”) filed a lawsuit in the San Diego County Superior against Kim Kelly, ND, MPH asserting claims related to the death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming us as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against the Company and various entities affiliated with Spectrum Laboratory Products, Inc., Spectrum Chemical Manufacturing Corp. and Spectrum Pharmacy Products, Inc. (collectively “Spectrum”). The cross-complaint seeks indemnity and contribution from the Company and Spectrum. The Company answered the claims filed by Dr. Kelly in October 2018. The case is currently in the discovery phase. Erick is seeking unspecified damages, interest, attorney’s fees and other costs. The Company believes the claims are meritless and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend against these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

General and Other

In the ordinary course of business, the Company may face various claims brought by third parties and it may, from time to time, make claims or take legal actions to assert its rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject the Company to litigation.

Indemnities

In addition to the indemnification provisions contained in the Company’s governing documents, the Company generally enters into separate indemnification agreements with each of the Company’s directors and officers. These agreements require the Company, among other things, to indemnify the director or officer against specified expenses and liabilities, such as attorneys’ fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual’s status or service as the Company’s director or officer, other than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by the Company. The Company also indemnifies its lessors in connection with its facility leases for certain claims arising from the use of the facilities. These indemnities do not provide for any limitation of the maximum potential future payments the Company could be obligated to make. Historically, the Company has not incurred any payments for these obligations and, therefore, no liabilities have been recorded for these indemnities in the accompanying condensed consolidated balance sheets.

Klarity License Agreement – Related Party

The Company entered into a license agreement in April 2017 and as amended in April 2018, (the “Klarity License Agreement”) with Richard L. Lindstrom, M.D., a member of its Board of Directors. Pursuant to the terms of the Klarity License Agreement, the Company licensed certain intellectual property and related rights from Dr. Lindstrom to develop, formulate, make, sell, and sub-license the topical ophthalmic solution Klarity used to protect and rehabilitate the ocular surface (the “Klarity Product”).

Under the terms of the Klarity License Agreement, the Company is required to make royalty payments to Dr. Lindstrom ranging from 3% - 6% of net sales, dependent upon the final formulation of the Klarity Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including: (i) an initial payment of \$50 upon execution of the Klarity License Agreement, (ii) a second payment of \$50 following the first \$50 in net sales of the Klarity Product; and (iii) a final payment of \$50 following the first \$100 in net sales of the Klarity Product. All of the above referenced milestone payments are payable at the Company’s election in cash or shares of the Company’s restricted common stock. Payments totaling \$55 and \$15 were made during the three months ended March 31, 2020 and 2019, respectively. \$29 and \$22 was incurred as royalty expense during the three months ended March 31, 2020 and 2019, respectively, and included in accounts payable to Dr. Lindstrom.

Injectable Asset Purchase Agreement – Related Party

In December 2019, the Company entered into an asset purchase agreement (the “Lindstrom APA”) with Dr. Lindstrom, a member of its Board of Directors. Pursuant to the terms of the Lindstrom APA, the Company acquired certain intellectual property and related rights from Dr. Lindstrom to develop, formulate, make, sell, and sub-license an ophthalmic injectable product (the “Lindstrom Product”).

Under the terms of the Lindstrom APA, the Company is required to make royalty payments to Dr. Lindstrom ranging from 2% to 3% of net sales, dependent upon the final formulation and patent protection of the Lindstrom Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including an initial payment of \$33 upon execution of the Lindstrom APA. Dr. Lindstrom was paid \$7 in cash during the three months ended March 31, 2020, and an additional \$38 was payable to Dr. Lindstrom at March 31, 2020. The Company incurred \$38 for royalty expenses related to the Lindstrom APA during the three months ended March 31, 2020.

Sales and Marketing Agreements

The Company has entered various sales and marketing agreements with certain organizations, to provide exclusive sales and marketing representation services to Harrow in select geographies in the U.S., in connection with our ophthalmic compounded formulations.

Under the terms of the sales and marketing agreements, the Company is required to make commission payments equal to 10% - 14% of net sales for products above and beyond the initial existing sales amounts. In addition, the Company is required to make periodic milestone payments to certain organizations in shares of the Company’s restricted common stock if net sales in the assigned territory reach certain future levels by the end of their terms, as applicable. \$83 and \$75 of stock-based payments were recorded and \$603 and \$542 were incurred under these agreements for commission expenses during the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020 the Company has recorded \$83 related to the stock-based payments in accounts payable and accrued expenses, and will record the amount as additional paid-in-capital upon the issuance of shares.

Asset Purchase, License and Related Agreements

The Company has acquired and sourced intellectual property rights related to certain proprietary innovations from certain inventors and related parties (the “Inventors”) through multiple asset purchase agreements, license agreements, strategic agreements and commission agreements. In general, these agreements provide that the Inventors will cooperate with the Company in obtaining patent protection for the acquired intellectual property and that the Company will use commercially reasonable efforts to research, develop and commercialize a product based on the acquired intellectual property. In addition, the Company has acquired a right of first refusal on additional intellectual property and drug development opportunities presented by these Inventors.

In consideration for the acquisition of the intellectual property rights, the Company is obligated to make payments to the Inventors based on the completion of certain milestones, generally consisting of: (1) a payment payable within 30 days after the issuance of the first patent in the United States arising from the acquired intellectual property (if any); (2) a payment payable within 30 days after the Company files the first investigational new drug application (“IND”) with the FDA for the first product arising from the acquired intellectual property (if any); (3) for certain of the Inventors, a payment payable within 30 days after the Company files the first new drug application with the FDA for the first product arising from the acquired intellectual property (if any); and (4) certain royalty payments based on the net receipts received by the Company in connection with the sale or licensing of any product based on the acquired intellectual property (if any), after deducting (among other things) the Company’s development costs associated with such product. If, following five years after the date of the applicable asset purchase agreement, the Company either (a) for certain of the Inventors, has not filed an IND or, for the remaining Inventors, has not initiated a study where data is derived, or (b) has failed to generate royalty payments to the Inventors for any product based on the acquired intellectual property, the Inventors may terminate the applicable asset purchase agreement and request that the Company re-assign the acquired technology to the Inventors. \$144 and \$191 were incurred under these agreements as royalty expenses and included in accounts payable at March 31, 2020 and 2019, respectively.

NOTE 15. SEGMENT INFORMATION AND CONCENTRATIONS

Management evaluates performance of the Company based on operating segments. Segment performance for its two operating segments is based on segment contribution. The Company's reportable segments consist of (i) its commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of ImprimisRx and Park businesses; and (ii) its start-up operations associated with pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for the segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. The Company does not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers and other like shared expenses.
- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.
- Other select revenues and operating expenses including R&D expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.
- Total assets including capital expenditures.

The Company defines segment net revenues as pharmaceutical compounded drug sales, licenses and other revenue derived from related agreements. Cost of sales within segment contribution includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

Selling, general and administrative expenses consist mainly of personnel-related costs, marketing and promotion costs, distribution costs, professional service costs, insurance, depreciation, facilities costs, transaction costs, and professional services costs which are general in nature and attributable to the segment.

Segment net revenues, segment operating expenses and segment contribution information consisted of the following for the three months ended March 31, 2020:

	For the Three Months Ended March 31, 2020		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	\$ 11,817	\$ -	\$ 11,817
Cost of sales	(3,626)	-	(3,626)
Gross profit	8,191	-	8,191
Operating expenses:			
Selling, general and administrative	6,640	44	6,684
Research and development	43	11	54
Segment contribution	<u>1,508</u>	<u>(55)</u>	<u>1,453</u>
Corporate			1,687
Research and development			349
Amortization			45
Operating loss			<u>\$ (628)</u>

	For the Three Months Ended March 31, 2019		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	\$ 12,290	\$ -	\$ 12,290
Cost of sales	(3,898)	-	(3,898)
Gross profit	8,392	-	8,392
Operating expenses:			
Selling, general and administrative	5,715	43	5,758
Research and development	125	136	261
Segment contribution	<u>2,552</u>	<u>(179)</u>	<u>2,373</u>
Corporate			2,719
Research and development			144
Amortization			66
Operating loss			<u>\$ (556)</u>

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the U.S.; therefore, total revenues are attributed to the U.S. All long-lived assets at March 31, 2020 and December 31, 2019 are located in the U.S.

The Company sells its compounded formulations to a large number of customers. No customer accounted for more than 10% of the Company's total pharmacy sales for the three months ended March 31, 2020 and 2019.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 78% and 67% of active pharmaceutical ingredient purchases during the three months ended March 31, 2020 and 2019, respectively.

NOTE 16. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to March 31, 2020 through the filing date of this Quarterly Report. Based on its evaluation, no events other than those described below need to be disclosed.

Second Amendment to SWK Loan

On April 1, 2020, the Company and several of its wholly owned subsidiaries entered into a second amendment (the "SWK Amendment") to the SWK Loan, with SWK. A summary of the material changes contained in the SWK Amendment are as follows:

- SWK agreed to make available to the Company, and the Company drew down on, an additional principal amount of one million dollars (\$1,000,000);
- The definition of the first amortization date was changed to August 14, 2020, permitting the Company to pay interest only on the principal amount loaned for the next payment (payments are due on a quarterly basis) following the SWK Amendment; and
- The interest payment due May 14, 2020 will be paid in kind by increasing the principal amount of the term loans by an amount equal to the interest that has accrued.

Paycheck Protection Program Loan

In April 2020, the Company entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the "PPP Loan") in the principal amount of \$1,967 and received cash proceeds of the same amount, pursuant to the Paycheck Protection Program (the "PPP") under the Federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted March 27, 2020. The PPP is administered by the U.S. Small Business Administration.

Under the terms of the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Loan is two years, unless sooner required in connection with an event of default under the PPP Loan. To the extent the PPP Loan amount is not forgiven under the PPP, the Company is obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the PPP Loan, until the maturity date.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, the Company may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during the eight-week period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments (it being anticipated that at least 75% of the loan amount will be required to be used for eligible payroll costs); the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible expenses during the covered eight-week period will qualify for forgiveness. While the Company intends to use proceeds from the PPP Loan for such qualifying expenses, in particular maintaining continuity of its payroll and workforce (including staff critical to the timely production and dispensing of medicines the Company produces), no assurance can be provided that the Company will obtain forgiveness of the PPP Loan in whole or in part.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto contained in Part I, Item 1 of this Quarterly Report on Form 10-Q (this “Quarterly Report”). Our condensed consolidated financial statements have been prepared and, unless otherwise stated, the information derived therefrom as presented in this discussion and analysis is presented, in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

The information contained in this Quarterly Report is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Quarterly Report and in our other reports filed with the U.S. Securities and Exchange Commission (the “SEC”), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and subsequent reports, which discuss our business in greater detail. As used in this discussion and analysis, unless the context indicates otherwise, the terms the “Company”, “Harrow” “we”, “us” and “our” refer to Harrow Health, Inc. and its consolidated subsidiaries, consisting of Park Compounding, Inc., ImprimisRx, LLC, ImprimisRx NJ, LLC dba ImprimisRx, Imprimis NJOF, LLC, Radley Pharmaceuticals, Inc., Mayfield Pharmaceuticals, Inc., and Stowe Pharmaceuticals, Inc. In this discussion and analysis, we refer to our consolidated subsidiaries ImprimisRx, LLC, ImprimisRx NJ, LLC and Imprimis NJOF, LLC collectively as “ImprimisRx.”

In addition to historical information, the following discussion contains forward-looking statements regarding future events and our future performance. In some cases, you can identify forward-looking statements by terminology such as “will”, “may”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “forecasts”, “potential” or “continue” or the negative of these terms or other comparable terminology. All statements made in this Quarterly Report other than statements of historical fact are forward-looking statements. These forward-looking statements involve risks and uncertainties and reflect only our current views, expectations and assumptions with respect to future events and our future performance. If risks or uncertainties materialize or assumptions prove incorrect, actual results or events could differ materially from those expressed or implied by such forward-looking statements. Risks that could cause actual results to differ from those expressed or implied by the forward-looking statements we make include, among others, risks related to: the impact of the COVID-19 pandemic on our financial condition, liquidity or results of operations; our ability to successfully implement our business plan, develop and commercialize our proprietary formulations in a timely manner or at all, identify and acquire additional proprietary formulations, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our previous acquisitions and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions; regulatory and legal risks and uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general; physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally; our limited operating history; and the other risks and uncertainties described under the heading “Risk Factors” in Part II, Item 1A of this Quarterly Report. You should not place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date they are made and, except as required by law, we undertake no obligation to revise or publicly update any forward-looking statement for any reason.

Overview

Our business specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace through our subsidiaries and deconsolidated companies. We own one of the nation’s leading ophthalmology pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, we also have equity positions in Eton Pharmaceuticals, Inc. (“Eton”), Surface Pharmaceuticals, Inc. (“Surface”), and Melt Pharmaceuticals, Inc. (“Melt”), all companies that began as subsidiaries of Harrow. More recently, we founded drug development subsidiaries Mayfield Pharmaceuticals, Inc. (“Mayfield”), Radley Pharmaceuticals, Inc. (“Radley”), and Stowe Pharmaceuticals, Inc. (“Stowe”). During 2020, we intend to launch a new business called Visionology. We also own royalty rights in various drug candidates being developed by Surface, Melt, Radley and Mayfield. We intend to continue to create and hold equity and royalty rights in new businesses that commercialize drug candidates that are internally developed or otherwise acquired or licensed from third parties.

ImprimisRx

ImprimisRx is our ophthalmology focused pharmaceutical compounding business. We offer to over 7,000 physician customers and their patients critical medicines to meet their needs that are unmet by commercially available drugs. We make our formulations available at prices that are, in most cases, lower than non-customized commercial drugs. Our current ophthalmology formulary includes over twenty compounded formulations, many of which are patented or patent-pending, and are customizable for the specific needs of a patient. Some examples of our compounded medications are various combinations of drugs formulated into one bottle and numerous preservative free formulations. Depending on the formulation, the regulations of a specific state and ultimately the needs of the patient, ImprimisRx products may be dispensed as patient-specific medications from our 503A pharmacy, or for in-office use, made according to current good manufacturing practices (or cGMPs) or other U.S. Food and Drug Administration (“FDA”) guidance documents, in our FDA-registered NJOF outsourcing facility.

Visionology

Visionology is expected to be an online eye health platform. Visionology will leverage our experience in the ophthalmic pharmaceutical business as well as our relationships with eyecare professionals across the United States. We expect to launch a proof-of-concept model for Visionology during the summer of 2020 within a certain region of the U.S., and if successful, expand the launch on a nationwide basis later in 2020 and/or 2021.

Pharmaceutical Compounding Businesses

Pharmaceutical Compounding

Pharmaceutical compounding is the science of combining different active pharmaceutical ingredients (APIs), all of which are approved by the FDA (either as a finished form product or as a bulk drug ingredient) and excipients, to create specialized pharmaceutical preparations. Physicians and healthcare institutions use compounded drugs when commercially available drugs do not optimally treat a patient’s needs. In many cases, compounded drugs, such as ours, have wide market utility and may be clinically appropriate for large patient populations. Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles.

Almost all of our sales revenue is derived from making, selling and dispensing our compounded prescription drug formulations as cash pay transactions between us and our end-user customer. As such, the majority of our commercial transactions do not involve distributors, wholesalers, insurance companies, pharmacy benefit managers or other middle parties. By not being reliant on insurance company formulary inclusion and pharmacy benefit manager payment clawbacks, we are able to simplify the prescription transaction process. We believe the outcome of our business model is a simple transaction, involving a patient-in-need, a physician’s diagnosis, a fair price and great service for a quality pharmaceutical product. We sell our products through a network of employees and independent contractors and we dispense our formulations in all 50 states, Puerto Rico and in selected markets outside the United States.

Our Compounding Facilities

Pharmaceutical compounding businesses are governed by Sections 503A and 503B of the Federal Food Drug and Cosmetic Act (the “FDCA”). Section 503A of the FDCA provides that a pharmacy is only permitted to compound a drug for an individually identified patient based on a prescription for a patient, and is only permitted to distribute the drug interstate if the pharmacy is licensed to do so in the states where it is compounded and where the medication is received.

Section 503B of the FDCA provides that a pharmacy engaged in preparing sterile compounded drug formulations may voluntarily elect to register as an “outsourcing facility.” Outsourcing facilities are permitted to compound large quantities of drugs without a prescription and distribute them out of state with certain limitations such as the formulation appearing on the FDA’s drug shortage list or the bulk drug substances contained in the formulations appearing on the FDA’s “clinical need” list. Entities voluntarily registering with FDA as outsourcing facilities are subject to additional requirements that do not apply to compounding pharmacies (operating under Section 503A of the FDCA), including adhering to standards such as current good manufacturing practices (cGMP) or other FDA guidance documents and being subject to regular FDA inspection.

We operate two compounding facilities located in Ledgewood, New Jersey. Our New Jersey operations are comprised of two separate entities and facilities, one of which is registered with the FDA as an outsourcing facility (“NJOF”) under Section 503B of the FDCA. The other New Jersey facility (“RxNJ”), is a licensed pharmacy operating under Section 503A of the FDCA. All products that we sell, produce and dispense are made in the United States.

We believe that, with our current compounding pharmacy facilities and licenses and FDA registration of NJOF, we have the infrastructure to scale our business appropriately under the current regulatory landscape and meet the potential growth in demand we are targeting. We plan to invest in one or both of our facilities to further their capacity and efficiencies. Also, we may seek to access greater pharmacy and production related redundancy and markets through acquisitions, partnerships or other strategic transactions.

Pharmaceutical Development Businesses

We have ownership interests in Eton, Surface, Melt, Mayfield, Stowe and Radley and hold royalty interests in certain of their drug candidates. These companies are pursuing market approval for their drug candidates under the FDCA, including in some instances under the abbreviated pathway described in Section 505(b)(2) which permits the submission of a new drug application (“NDA”) where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. In 2018 and 2019, we formed and created subsidiaries named Radley, Mayfield, and Stowe, which we intend to operate similar to Eton, Surface and Melt. In addition, we intend to create additional subsidiaries that will be focused on the development and FDA approval of certain proprietary drug formulations that we currently own, will in-license/acquire and/or otherwise develop.

Consolidated Businesses

Stowe Pharmaceuticals, Inc.

Stowe is a consolidated subsidiary of Harrow that was formed in 2019, focused on the development of its proprietary ophthalmic drug candidate STE-006. STE-006 is a patented, new chemical entity, small molecule topical drug candidate intended to treat various bacterial, fungal, and viral infections in the eye and ear. In initial preclinical models, STE-006 was shown to be significantly more effective compared to current conventional therapies against numerous bacterial and viral pathogens, including strains of methicillin-resistant staphylococcus aureus, or MRSA, and herpes simplex virus. STE-006 has several patents covering matter of composition, methods of production, methods of use and molecule, which are valid until 2038.

We own 2,500,000 shares of Stowe common stock, and control 70% of the equity and voting interests issued and outstanding of Stowe at March 31, 2020.

Mayfield Pharmaceuticals, Inc.

Mayfield, a consolidated subsidiary of Harrow, is a development-stage pharmaceutical company focused on consequential products that address the conspicuous unmet needs of patients. Its development programs focus on using known molecules in dosage forms for new indications, and by developing new chemical entities with known mechanisms of action. Mayfield recently licensed worldwide rights to a first-in-class antimicrobial drug candidate, called MAY-66, which is being studied to treat recurrent bacterial vaginosis. In February 2019, Mayfield acquired drug formulation assets and intellectual property, including three recently issued patents, for MAY-44, a drug candidate for the treatment of dyspareunia, or pain experienced by women during sexual intercourse. In addition to MAY-44, Mayfield is also developing MAY-88 for patients suffering from interstitial cystitis, which it will acquire from Harrow at the closing of a deconsolidating transaction.

We own 2,500,000 shares of Mayfield common stock, and control 79% of the equity and voting interests issued and outstanding of Mayfield at March 31, 2020. We are currently pursuing a deconsolidating transaction for Mayfield. Once deconsolidated, we expect Mayfield to be run by an experienced life science executive, that we have recently contracted with.

Radley Pharmaceuticals, Inc.

Radley, a consolidated subsidiary of Harrow, is a development-stage pharmaceutical company focused on the development of proprietary drug candidates focused on rare diseases. Radley currently has three drug programs in its pipeline. During January 2020, and prior to initiating significant development activities and costs related to these drug programs, we met with the FDA to establish and understand the expected clinical and regulatory path to approval for Radley’s lead drug program. Conceptually, the FDA agreed with our clinical program design, and we are currently considering options related to the next steps of the drug candidates development. We are also pursuing investigator-initiated studies for some of Radley’s drug candidates with two well-known healthcare institutions based in the New York and Boston areas. We believe this approach will allow us to better understand and weigh the economic costs, clinical feasibility and potential benefits associated with pursuing development activities associated with these drug programs. Radley is also pursuing additional asset acquisition and licensing opportunities with a focus in oncology-related therapies.

De-Consolidated Businesses

Eton Pharmaceuticals, Inc.

Eton is a pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Its pipeline includes several products and drug candidates in various stages of development across a variety of dosage forms. Eton's pipeline is focused on innovative 505(b)(2) products and obtaining FDA marketing approval for currently marketed but unapproved drugs.

In May 2017, Eton closed an offering of its Series A Preferred Stock and we lost our controlling interest in it. In November 2018, Eton completed an initial public offering of its common stock. We own 3,500,000 shares of Eton common stock, which is less than 20% of the equity and voting interests issued and outstanding of Eton as of March 31, 2020.

Surface Pharmaceuticals, Inc.

Surface is a development-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases and is seeking FDA approval for the commercialization of its drug candidates through the Section 505(b)(2) regulatory pathway under the FDCA. In 2017 and amended in April 2018, Harrow entered into asset purchase and license agreements (the "Surface License Agreements") and transferred to Surface its current drug pipeline, which consists of three proprietary drug candidates. Surface's patent-pending topical eye drop drug candidates, SURF-100 and SURF-200, utilize a patented delivery vehicle known as Klarity Drops ("Klarity"), that was invented by Harrow board member and Surface's chairman of the board, renowned ophthalmologist Dr. Richard Lindstrom.

During the fourth quarter of 2019, Surface filed an investigational new drug application ("IND") for its drug program SURF-201. SURF-201 is a novel steroid topical eye drop drug candidate for treating pain and inflammation post-ocular surgery. Surface submitted an IND for its lead drug candidate, SURF-100, in May 2020, for treating signs and symptoms associated with chronic dry eye disease. Surface also filed a third IND during the first half of 2020. We expect Surface may release certain clinical data related to these programs near the end of 2020 and beginning of 2021, however such clinical programs and related data may be delayed as a result of the ongoing COVID-19 pandemic.

In May and July 2018, Surface closed on an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements. We own 3,500,000 shares of Surface which is approximately 30% of the equity and voting interests as of March 31, 2020.

Melt Pharmaceuticals, Inc.

Melt is a development-stage pharmaceutical company focused on the development and commercialization of proprietary non-intravenous, sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval for its proprietary technologies, where possible. In December 2018, we entered into an Asset Purchase Agreement with Melt (the "Melt Asset Purchase Agreement"), and Harrow assigned to Melt the underlying intellectual property for Melt's current pipeline, including its lead drug candidate MELT-100. The core intellectual property Melt owns is a patented series of combination non-opioid sedation drug formulations that we estimate to have multitudinous applications. Pursuant to the terms of the Melt Asset Purchase Agreement, Melt is required to make royalty payments to the Company equal to 5% of net sales of MELT-100, while any patent rights remain outstanding, subject to other conditions.

MELT-100 is a novel, sublingually delivered, non-IV, opioid-free drug candidate being developed for procedural sedation. Melt is expecting to file an IND and begin its clinical program for MELT-100 in the summer of 2020, and if successful, begin enrollment for its Phase 3 studies for MELT-100 during 2021.

In January 2019, Melt closed an offering of its Series A Preferred Stock and we lost our controlling interest in it. We own 3,500,000 shares of Melt common stock, which is approximately 44% of the equity and voting interests issued and outstanding of Melt as of March 31, 2020.

Factors Affecting Our Performance

We believe the primary factors affecting our performance are our ability to increase revenues of our proprietary compounded formulations and certain non-proprietary products, grow and gain operating efficiencies in our pharmacy operations, optimize pricing and obtain reimbursement options for our proprietary compounded formulations, and continue to pursue development and commercialization opportunities for certain of our ophthalmology and other assets that we have not yet made commercially available as compounded formulations. We believe we have built a tangible and intangible infrastructure that will allow us to scale revenues efficiently in the long-term. All of these activities will require significant costs and other resources, which we may not have or be able to obtain from operations or other sources. See “Liquidity and Capital Resources” below.

Reimbursement Options

Our proprietary ophthalmic compounded formulations are currently primarily available on a cash-pay basis. However, we work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We may devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations and we have hired pharmacy billers to process certain existing reimbursement opportunities for certain formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the “Health Care Reform Law”), may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivably have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. We are communicating with government and third-party payors in order to make our formulations available to more patients and at optimized pricing levels. However, if government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance and opportunity for our formulations may be limited.

Additionally, we are making efforts to receive reimbursement and/or optimize the pricing for some of our currently available pharmaceutical compounded formulations, including applying for transitional pass-through reimbursement status for one of our formulations. Pass-through status allows for separate payment (i.e., outside the bundled payment) under Medicare Part B for new drugs and other medical technologies that meet well-established criteria specified by federal regulations governing CMS spending. We expect to hear from CMS before July 1, 2020, if we will be granted pass-through status for one of these formulations. Any efforts to attain optimized pricing or reimbursement for these or any of our other proprietary formulations could fail, which could make our products less attractive or unavailable to some patients or could reduce our margins.

Recent Developments

The following describes certain developments in 2020 to date that are important to understand our financial condition and results of operations. See the notes to our condensed consolidated financial statements included in this report for additional information about each of these developments.

COVID-19 Pandemic

A novel strain of coronavirus was first identified in Wuhan, China in December 2019. The disease caused by it, COVID-19, was declared a global pandemic by the World Health Organization in March 2020. On March 18, 2020, CMS released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. In addition to limiting elective medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendation, and created significant volatility in financial markets.

In response to the pandemic and business disruptions, first and foremost, we have prioritized the health and safety of our employees, customers, suppliers and others with whom we partner in our business activities. We have instructed employees to work from home when possible and to maintain recommended physical distancing when working in our facilities. We also have eliminated non-essential in-person contact with customers, suppliers and other third parties.

Many of the Company's customers use its drugs in procedures impacted by the CMS guidance to limit elective procedures. In addition, the Company and our business partners need access to healthcare providers and facilities to conduct clinical trials and other activities required to achieve regulatory clearance of products under development. We are carefully monitoring rapidly evolving changes in healthcare delivery systems and may adjust our operating and product development plans accordingly.

Given the unprecedented and dynamic nature of the COVID-19 pandemic, we cannot reasonably estimate the impacts it may have on our financial condition, results of operations or cash flows in the future. However, we expect that reductions in elective procedures in response to CMS guidance will have an adverse impact, which may be material, on our future revenues, profitability and cash flows. The extent and duration of that impact will depend upon the extent of procedure postponements and the duration of the pandemic. Near the beginning of May 2020, some U.S. states and geographies began easing restrictions associated with the COVID-19 pandemic including those restrictions related to elective procedures. We are hopeful sales of our products will return to historical norms and trends as other states and governmental authorities ease restrictions associated with elective procedures and the COVID-19 pandemic.

SWK Amendment

In April 2020, the Company and several of its wholly owned subsidiaries entered into a second amendment (the "SWK Amendment") to the term loan and security agreement dated as of July 19, 2017, as amended (the "SWK Loan"), with SWK Funding LLC, as lender and collateral agent, and certain other lenders (collectively, "SWK"). A summary of the material changes contained in the SWK Amendment are as follows:

- SWK agreed to make available to the Company, and the Company drew down on, an additional principal amount of \$1,000,000;
- The definition of the first amortization date was changed to August 14, 2020, permitting the Company to pay interest only on the principal amount loaned for the next payment (payments are due on a quarterly basis) following the SWK Amendment; and
- The interest payment due May 14, 2020 will be paid in-kind by increasing the principal amount of the term loans by an amount equal to the interest that has accrued.

PPP Loan

In April 2020, we entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the "PPP Loan") in the principal amount of \$1,967,100 and received cash proceeds of the same amount, pursuant to the Paycheck Protection Program (the "PPP") under the Federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted March 27, 2020. The PPP is administered by the U.S. Small Business Administration.

Under the terms of the PPP Loan, interest accrues on the outstanding principal at the rate of 1.0% per annum. The term of the PPP Loan is two years, unless sooner required in connection with an event of default under the PPP Loan. To the extent the PPP Loan amount is not forgiven under the PPP, the Company is obligated to make equal monthly payments of principal and interest, beginning seven months from the date of the Note, until the maturity date.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. Under the PPP, the Company may apply for and be granted forgiveness for all or part of the PPP Loan. The amount of loan proceeds eligible for forgiveness is based on a formula that takes into account a number of factors, including the amount of loan proceeds used by the Company during the eight-week period after the loan origination for certain purposes including payroll costs, interest on certain mortgage obligations, rent payments on certain leases, and certain qualified utility payments (it being anticipated that at least 75% of the loan amount will be required to be used for eligible payroll costs); the employer maintaining or rehiring employees and maintaining salaries at certain levels; and other factors. Subject to the other requirements and limitations on loan forgiveness, only loan proceeds spent on payroll and other eligible expenses during the covered eight-week period will qualify for forgiveness. While we intend to use proceeds from the PPP Loan for such qualifying expenses, in particular maintaining continuity of our payroll and workforce (including staff critical to the timely production and dispensing of medicines we make), no assurance can be provided that we will obtain forgiveness of the PPP Loan in whole or in part.

Results of Operations

The following period-to-period comparisons of our financial results for the three months ended March 31, 2020 and 2019, are not necessarily indicative of results for the current period or any future period.

Revenues

Our revenues include amounts recorded from sales of proprietary compounded formulations and revenues received from royalty payments owed to us pursuant to out-license arrangements.

The following presents our revenues for the three months ended March 31, 2020 and 2019:

	For the Three Months Ended		\$
	March 31,		
	2020	2019	Variance
Product sales, net	\$ 11,810,000	\$ 12,283,000	\$ (473,000)
License revenues	7,000	7,000	-
Total revenues	\$ 11,817,000	\$ 12,290,000	\$ (473,000)

The decrease in revenues between periods was largely attributable to the COVID-19 pandemic and CMS guidance to limit elective procedures. Our gross ophthalmology-related sales were approximately \$10,994,000 for the three months ended March 31, 2020, compared to \$10,976,000 during the same period last year. Net revenues generated from NJOF totaled \$7,935,000 and \$7,398,000 during the three months ended March 31, 2020 and 2019, respectively.

Cost of Sales

Our cost of sales includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

The following presents our cost of sales for the three months ended March 31, 2020 and 2019:

	For the Three Months Ended		\$
	March 31,		
	2020	2019	Variance
Cost of sales	\$ 3,626,000	\$ 3,898,000	\$ (272,000)

The decrease in our cost of sales between periods was largely attributable to a decrease in unit volumes sold and partially offset by continued improved utilization of capacity at our compounding facilities.

Gross Profit and Margin

	For the Three Months Ended		\$
	March 31,		
	2020	2019	Variance
Gross Profit	\$ 8,191,000	\$ 8,392,000	\$ (201,000)
Gross Margin	69.4%	68.3%	0.6%

The increase in gross margin between periods is largely attributable to increased efficiencies in our production process, extension of beyond using dating, or BUD, of some of our products, utilization of capacities as a result of increased output and an increase in sales prices.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include personnel costs, including wages and stock-based compensation, corporate facility expenses, and investor relations, consulting, insurance, filing, legal and accounting fees and expenses as well as costs associated with our marketing activities and sales of our proprietary compounded formulations and other non-proprietary pharmacy products and formulations.

The following presents our selling, general and administrative expenses for the three months ended March 31, 2020 and 2019:

	For the Three Months Ended		\$
	March 31,		
	2020	2019	Variance
Selling, general and administrative	<u>\$ 8,416,000</u>	<u>\$ 8,543,000</u>	<u>\$ (127,000)</u>

The decrease in selling, general and administrative expenses between periods was largely attributable to decreased legal expenses incurred associated with ongoing litigation, and sales related expenses.

Research and Development Expenses

Our research and development expenses primarily include expenses related to the development of acquired intellectual property, investigator-initiated research and evaluations and other costs related to the clinical development of our assets.

The following presents our research and development expenses for the three months ended March 31, 2020 and 2019:

	For the Three Months Ended		\$
	March 31,		
	2020	2019	Variance
Research and development	<u>\$ 403,000</u>	<u>\$ 405,000</u>	<u>\$ (2,000)</u>

Research and development expenses between periods was primarily attributable to formulation development studies for new ophthalmic formulations and clinical programs related to our drug development segment during the three months ended March 31, 2020.

Interest Expense, net

Interest expense, net was \$560,000 for the three months ended March 31, 2020, compared to \$603,000 the same period last year. The decrease during the period ending March 31, 2020 compared to the same period in 2019 was primarily due to interest expense recognition related to a decrease in the amortization of our finance lease obligations.

Investment Gain (Loss) from Melt, net

During the three months ended March 31, 2020, we recorded a loss of \$546,000 for our share of losses based on our ownership of Melt. During the three months ended March 31, 2019, we recorded a net gain of \$5,525,000 related to our investment in Melt. We recorded a gain of \$5,810,000 for the deconsolidation of Melt, and a loss of \$285,000 for our share of losses based on our ownership of Melt. We began using equity method accounting for our investment in Melt beginning on January 30, 2019, the date we no longer had a controlling interest, prior to that date, their losses were consolidated within our statements of operations.

Investment Loss from Surface, net

During the three months ended March 31, 2020 and 2019, we recorded a loss of \$339,000 and \$243,000, respectively, for our share of losses based on our ownership of Surface.

Investment Gain (Loss) from Eton, net

We recorded a loss of \$(10,850,000) and gain of \$6,580,000 related to the change in fair market value of Eton's common stock for the three months ended March 31, 2020 and 2019, respectively.

Other Income (Expense), net

During the three months ended March 31, 2019, we recorded other income, net of \$630,000. This was the result of income of \$630,000 related to expenses that were paid by us and will be reimbursed by Melt following its deconsolidation. There were no similar amounts during the three months ended March 31, 2020.

Net Loss

The following table presents our net loss for the three months ended March 31, 2020 and 2019:

	For the Three Months Ended March 31,	
	2020	2019
Net (loss) income attributable to Harrow Health, Inc.	\$ (12,907,000)	\$ 11,358,000
Net (loss) income per share, basic	\$ (0.50)	\$ 0.46
Net (loss) income per share, diluted	\$ (0.50)	\$ 0.43

Financial Information About Segments and Geographic Areas

Management evaluates performance of the Company based on operating segments. Segment performance for our two operating segments are based on segment contribution. Our reportable segments consist of (i) our commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of our ImprimisRx and Park businesses; and (ii) the start-up operations associated with our pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for the segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. We do not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with litigation and other legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers, and other like shared expenses.
- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.
- Other select revenues and operating expenses including R&D expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.
- Total assets including capital expenditures.

The Company defines segment net revenues as pharmaceutical compounded drug sales, licenses and other revenue derived from related agreements.

Cost of sales within segment contribution includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

Selling, general and administrative expenses consist mainly of personnel-related costs, marketing and promotion costs, distribution costs, professional service costs, insurance, depreciation, facilities costs, transaction costs, and professional services costs which are general in nature and attributable to the segment.

See Note 15 to our condensed consolidated financial statements included in this Quarterly Report for more information about our reportable segments.

Liquidity and Capital Resources

Liquidity

Our cash on hand (including restricted cash) at March 31, 2020 was \$4,124,000, compared to \$4,949,000 at December 31, 2019. Since inception, July 24, 1998, through March 31, 2020, we have incurred aggregate losses of \$86,950,000. These losses are primarily due to selling, general and administrative, and research and development expenses incurred in connection with developing and seeking regulatory approval for a former drug candidate, which activities we have now discontinued, the development and commercialization of novel compounded formulations and the development of our pharmacy operations.

As of the date of this Quarterly Report, we believe that cash and cash equivalents of \$3,924,000 and restricted investments of \$200,000, totaling approximately \$4,124,000 at March 31, 2020, along with \$1,000,000 from the April draw down on the SWK Loan and \$1,967,100 from the PPP Loan will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. We also may consider the sale of certain assets including, but not limited to, part of, or all of, our ownership interest in Eton, Surface, Melt, and/or any of our consolidated subsidiaries. However, our plans for this period may change, our estimates of our operating expenses, capital expenditures and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies or other strategic transactions that involve large expenditures or we may experience growth more quickly or on a larger scale than we expect, any of which could result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing earlier than we expect to support our operations.

We expect to use our current cash position and funds generated from our operations and any financing to pursue our business plan, which includes developing and commercializing compounded formulations and technologies, integrating and developing our compounding operations, pursuing potential future strategic transactions as opportunities arise, including potential acquisitions of additional pharmacy, outsourcing facilities, drug company and manufacturers, and/or assets or technologies, and otherwise fund our operations. We may also use our resources to conduct clinical trials or other studies in support of our formulations or any drug candidate for which we pursue FDA approval, to pursue additional development programs or to explore other development opportunities.

Net Cash Flow

The following provides detailed information about our net cash flows:

	For the Three months Ended	
	March 31,	
	2020	2019
Net cash used in:		
Operating activities	\$ (550,000)	\$ (1,476,000)
Investing activities	(273,000)	(324,000)
Financing activities	(2,000)	(773,000)
Net change in cash and cash equivalents	(825,000)	(2,573,000)
Cash and cash equivalents at beginning of the period	4,949,000	6,838,000
Cash and cash equivalents at end of the period	<u>\$ 4,124,000</u>	<u>\$ 4,265,000</u>

Operating Activities

Net cash used in operating activities was \$(550,000), compared to \$(1,476,000) in operating activities during the same period in the prior year. The decrease in net cash used in operating activities during the periods was mainly attributed to deferral of bonus payments and other accrued expenses as part of the actions taken by the Company in response to the COVID-19 pandemic.

Investing Activities

Net cash used in investing activities during the three months ended March 31, 2020 and 2019 was \$(273,000) and \$(324,000), respectively. Cash used in investing activities in 2020 and 2019 was primarily associated with equipment purchases and upgrades and investments in our intellectual property portfolio.

Financing Activities

Net cash used in financing activities during the three months ended March 31, 2020 and 2019 was \$(2,000) and \$(773,000), respectively. Cash used in financing activities during the three months ended March 31, 2020 was related to principal payments on our finance lease.

Sources of Capital

Our principal sources of cash consist of cash provided by operating activities from our pharmaceutical compounding business. We may also sell some or all of our ownership interests in Eton, Surface, Melt or our other subsidiaries. We produced cash from operations during 2018 and 2019; however, we currently are experiencing a downturn in revenues mostly as a result of the COVID-19 pandemic which will have an impact on our ability to produce cash in the current year. In addition, prior to 2017, we had not generated sufficient revenues to support our operations and may not be able to do so in the future.

The changing trends and overall economic outlook in light of the COVID-19 pandemic, including the related interim stay-at-home orders and bans on elective surgeries, have created uncertainty surrounding our operating outlook and may impact our future operating results. As a result, we may need significant additional capital to support our business plan and fund our proposed business operations. We may receive additional proceeds from the exercise of stock purchase warrants that are currently outstanding. We may also seek additional financing from a variety of sources, including other equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or any other financing transaction. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration or licensing arrangements or sales of assets, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies or formulations, or grant licenses on terms that are not favorable to us. If we raise funds by incurring additional debt, we may be required to pay significant interest expenses and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming they would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities, such as the financial and operating covenants included in the agreements governing the SWK Loan. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which would adversely impact our financial results.

We may be unable to obtain financing when necessary as a result of, among other things, our performance, general economic conditions, conditions in the pharmaceuticals and pharmacy industries, or our operating history, including our past bankruptcy proceedings. In addition, the fact that we have a limited history of profitability could further impact the availability or cost to us of future financings. As a result, sufficient funds may not be available when needed from any source or, if available, such funds may not be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs when needed, then we may need to forego pursuit of potentially valuable development or acquisition opportunities, we may not be able to continue to operate our business pursuant to our business plan, which would require us to modify our operations to reduce spending to a sustainable level by, among other things, delaying, scaling back or eliminating some or all of our ongoing or planned investments in corporate infrastructure, business development, sales and marketing and other activities, or we may be forced to discontinue our operations entirely.

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures***Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted pursuant to the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

Under the supervision and with the participation of our principal executive officer and principal financial officer, our management conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act, as they existed on March 31, 2020. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of March 31, 2020, the end of the period covered by this report.

Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended March 31, 2020, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal control over financial reporting due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 pandemic on our internal controls to minimize the impact on their design and operating effectiveness.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings

Novel Drug Solutions et al.

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA, (collectively “NDS”) filed a lawsuit against us in the U.S. District Court of Delaware asserting claims for breach of contract. The claims stem from an asset purchase agreement between us and NDS entered into in 2013. In July 2019, NDS filed a second amended complaint which added a claim related to its purported termination of the APA. In October 2019, NDS voluntarily dismissed all claims related to breach of contract, leaving only claims related to the scope of the post termination obligations to be litigated. NDS is seeking unspecified damages, interest, attorney’s fees and other costs. We believe the claims are meritless and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend against these allegations. Nonetheless, we cannot predict the eventual outcome of this litigation and it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

Product and Professional Liability

Product and professional liability litigation represents an inherent risk to all firms in the pharmaceutical and pharmacy industry. We utilize traditional third-party insurance policies with regard to our product and professional liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

John Erick et al.

In January 2018, John Erick and Deborah Ferrell, successors-in-interest and heirs of Jade Erick, (collectively “Erick”) filed a lawsuit in the San Diego County Superior against Kim Kelly, ND, MPH asserting claims related to death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming us as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against us and various Spectrum entities. The cross-complaint seeks indemnity and contribution from us and Spectrum. We answered the claims filed by Dr. Kelly in October 2018. The case is currently in the discovery phase. Erick is seeking unspecified damages, interest, attorney’s fees and other costs. We believe the claims are meritless and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend against these allegations. Nonetheless, we cannot predict the eventual outcome of this litigation and it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

General and Other

In the ordinary course of business, we may face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject us to litigation.

Item 1A. Risk Factors

You should carefully consider the following risk factors in addition to the other information contained in this Quarterly Report. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks. You should consider all of the factors described in this section as well as the risk factors and the other information in our Annual Report on Form 10-K including our audited financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” when evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investments. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

The COVID-19 pandemic has had an adverse effect on our business and results of operations and is expected to continue to have further adverse effects, which could be material, on our business, results of operations, financial condition, liquidity, and capital investments.

On March 11, 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted supply chains and created significant volatility in financial markets. We have implemented business policies intended to protect our employees from the spread of COVID-19. Those policies include employees working from home when possible and employees in our facilities increasing physical distancing.

On March 18, 2020, the Centers for Medicare & Medicaid Services (“CMS”) released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. Many of our customers use our products in procedures impacted by the guidance. In addition to limiting medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. We cannot predict the duration or scope of the pandemic, actions that may be taken by governments and businesses in response to the pandemic, or the impacts of the pandemic on healthcare systems. The impacts of the pandemic may include, but are not limited to:

- Reduced revenues from our customers, including our major customers, whose products are impacted by CMS guidance to limit elective medical procedures;
- Diminished ability or willingness of third parties to market, distribute and sell our products, due to reduced demand from, or lack of access to, healthcare facilities and providers;
- Diminished ability, or inability, to complete clinical trials and other activities required to achieve regulatory clearance of our products under development due to lack of access to healthcare facilities, healthcare providers and patients;
- Diminished or lost access to third party service providers that we use in our research and development or marketing efforts;
- Reduced cash flow from our operations due to reductions in revenues or collections from our customers and increases in operating costs related to actions we have taken in response to the pandemic;
- Reduced business productivity due to inefficiencies in employees working from home or increasing physical distancing and other pandemic response protocols in our production facilities;
- Increased susceptibility to the risk of information technology security breaches and other disruptions due to increased volumes of remote access to our information systems from our employees working at home;
- Inability to source sufficient components used in our products due to disruptions in supply chains;
- Diminished ability to identify, evaluate and acquire, or effectively integrate, complementary businesses, products, materials or technologies due to travel restrictions, physical distancing protocols, and lack of access to third party service providers related to our development activities;
- Loss of manufacturing capacity, which could lead to failures to meet product delivery commitments, or increased operating costs if one of our facilities were to experience a COVID-19 outbreak;
- Difficulties in assessing and securing intellectual property rights due to lack of access to, or delayed responsiveness of, third party service providers or governmental agencies;
- Diminished ability to retain personnel over concerns about workplace exposure to COVID-19, or to hire and effectively train new personnel, due to physical distancing protocols; and
- Impairment of goodwill or other assets due to reductions in the fair value of our reporting units.

These and other factors relating to, or arising from, the pandemic could have material adverse effects on our business, results of operations, cash flows, financial condition, and capital investments. Actual or anticipated adverse effects on our cash flows or financial condition may lead us to seek additional funding. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. We cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or otherwise curtail our operations. Any of these events could materially harm our business and operating results.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of contract research organizations (or CROs), contractors and consultants, could be subject to power shortages, telecommunications failures, wildfires, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, such as the COVID-19 pandemic, and other natural or man-made disasters or business interruptions for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of our contract manufacturers or cell line storage facilities are affected by a man-made or natural disaster or other business interruption.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

From time to time, including recently as a result of the COVID-19 pandemic, global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate it may make any debt or equity financing more difficult to complete, more costly, and more dilutive. In the event the Company or one of its subsidiaries needed to access additional capital, failure to secure financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
31.1*	<u>Certification of Mark L. Baum, principal executive officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.</u>
31.2*	<u>Certification of Andrew R. Boll, principal financial and accounting officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.</u>
32.1**	<u>Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Mark L. Baum, principal executive officer, and Andrew R. Boll, principal financial and accounting officer.</u>
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, has been formatted in Inline XBRL.

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

Harrow Health, Inc.

Dated: May 11, 2020

By: */s/ Mark L. Baum*

Mark L. Baum
Chief Executive Officer and Director
(Principal Executive Officer)

By: */s/ Andrew R. Boll*

Andrew R. Boll
Chief Financial Officer (Principal Financial and Accounting Officer)

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Mark L. Baum, certify that:

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

Date: May 11, 2020

/s/ Mark L. Baum

Mark L. Baum
Chief Executive Officer
Principal Executive Officer

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Andrew R. Boll, certify that:

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

Date: May 11, 2020

/s/ Andrew R. Boll

Andrew R. Boll
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION REQUIRED BY
SECTION 1350 OF TITLE 18 OF THE UNITED STATES CODE**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned hereby certifies in his capacity as the specified officer of Harrow Health, Inc. (the "Company"), that, to the best of his knowledge, the Quarterly Report of the Company on Form 10-Q for the fiscal quarter ended March 31, 2020 fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented in the financial statements included in such report.

Date: May 11, 2020

/s/ Mark L. Baum

Mark L. Baum
Chief Executive Officer
(Principal Executive Officer)

Date: May 11, 2020

/s/ Andrew R. Boll

Andrew R. Boll
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies this Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.
