# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

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

For the quarterly period ended September 30, 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)

102 Woodmont Blvd., Suite 610 Nashville, Tennessee (Address of principal executive offices)

П

**45-0567010** (I.R.S. Employer Identification No.)

**37205** (Zip code)

Accelerated filer

Smaller reporting company

Emerging growth company

 $\times$ 

X

(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  $\boxtimes$  No  $\square$ 

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  $\boxtimes$  No  $\square$ 

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

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.  $\Box$ 

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 Global Market

As of November 6, 2020, there were 25,745,967 shares of the registrant's common stock, \$0.001 par value, outstanding.

# HARROW HEALTH, INC.

# Table of Contents

		Page
Part I	FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited)	3
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	30
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	41
Item 4.	Controls and Procedures	41
Part II	OTHER INFORMATION	
Item 1.	Legal Proceedings	42
Item 1A.	Risk Factors	42
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	45
Item 3.	Defaults Upon Senior Securities	45
Item 4.	Mine Safety Disclosures	45
Item 5.	Other Information	45
Item 6.	Exhibits	45
	Signatures	46
	2	

# PART I FINANCIAL INFORMATION

# Item 1. Financial Statements

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

	Sep	tember 30, 2020	De	ecember 31, 2019
	(u	naudited)		
ASSETS				
Current assets				
Cash and cash equivalents, including restricted cash of \$200	\$	5,727	\$	4,949
Investment in Eton Pharmaceuticals		27,650		25,200
Accounts receivable, net		2,195		2,009
Inventories		3,974		3,301
Prepaid expenses and other current assets		1,431		1,308
Total current assets		40,977		36,767
Property, plant and equipment, net		4,773		5,375
Operating lease right-of-use assets		6,945		6,559
Intangible assets, net		1,958		2,337
Investment in Surface Ophthalmics		2,053		3,747
Investment in Melt Pharmaceuticals		2,432		3,968
Goodwill		332		332
TOTAL ASSETS	\$	59,470	\$	59,085
LIABILITIES AND STOCKHOLDERS' EQUITY			-	
Current liabilities				
Accounts payable and accrued expenses	\$	5,691	\$	7,702
Accrued payroll and related liabilities		3,692		2,117
Deferred revenue and customer deposits		63		57
Current portion of paycheck protection program loan payable		1,138		-
Current portion of loan payable, net of unamortized debt discount		2,612		1,772
Current portion of operating lease liabilities		579		629
Current portion of finance lease obligations		7		7
Total current liabilities		13,782		12,284
Operating lease liabilities, net of current portion		6,780		6,338
Finance lease obligations, net of current portion		20		26
Accrued expenses, net of current portion		800		800
Paycheck protection program loan payable, net of current portion		829		-
Loan payable, net of current portion and unamortized debt discount		12,331		12,219
TOTAL LIABILITIES		34,542		31,667
COMMITMENTS AND CONTINGENCIES				
STOCKHOLDERS' EQUITY				
Common stock, \$0.001 par value, 50,000,000 shares authorized, 25,652,169 and				
25,526,931 shares issued and outstanding at September 30, 2020 and December 31,				
2019, respectively		26		26
Additional paid-in capital		103,798		101,728
Accumulated deficit		(78,549)		(74,043)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY		25,275		27,711
Noncontrolling interests		(347)		(293)
TOTAL STOCKHOLDERS' EQUITY		24,928		27,418
TOTAL LIABILITIES AND EQUITY	\$	59,470	\$	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)

	Thre I Septe	For the the Months Ended ember 30, 2020		For the hree Months Ended eptember 30, 2019		For the fine Months Ended ptember 30, 2020		For the ine Months Ended ptember 30, 2019
Revenues:								
Product sales, net	\$	14,385	\$	12,748	\$	34,244	\$	38,540
Other revenues		14		7		32		21
Total revenues		14,399		12,755		34,276		38,561
Cost of sales		(3,696)		(4,061)		(10,526)		(13,184)
Gross profit		10,703		8,694		23,750		25,377
Operating expenses:								
Selling, general and administrative		8,436		8,608		23,806		25,399
Research and development		670		444		1,822		1,659
Impairment of long-lived assets		-		4,040		363		4,040
Total operating expenses		9,106		13,092		25,991		31,098
Income (loss) from operations		1,597		(4,398)		(2,241)		(5,721)
Other income (expense):								
Interest expense, net		(498)		(620)		(1,563)		(1,939)
Investment (loss) gain from Melt Pharmaceuticals,						(1.52.6)		4 51 5
net		(300)		(682)		(1,536)		4,517
Investment loss from Surface Ophthalmics, net		(756)		(400)		(1,694)		(904)
Investment gain (loss) from Eton Pharmaceuticals, net		8,575		(5,530)		2,450		700
Other income, net		8,575 5		(5,550)		2,430		630
-		7,026		(7,232)		(2,319)		3,004
Total other income (expense), net Income (loss) before income taxes		8,623		(11,630)		(4,560)		(2,717)
Income tax benefit, net		8,023		(11,050)		(4,500)		(2,717)
Total net income (loss) including noncontrolling			_		_	-	_	-
interests		8,623		(11,630)		(4,560)		(2,717)
Net loss attributable to noncontrolling interests		15		161		54		228
Net income (loss) attributable to Harrow Health, Inc.	\$	8,638	\$	(11,469)	\$	(4,506)	\$	(2,489)
Basic net income (loss) per share of common stock	\$	0.33	\$	(0.45)	\$	(0.17)	\$	(0.10)
Diluted net income (loss) per share of common stock	3 \$		\$	<u> </u>		(0.17)		<u> </u>
Weighted average number of shares of common stock	2	0.32	\$	(0.45)	\$	(0.17)	\$	(0.10)
outstanding, basic		25 021 572		25 592 009		25 990 554		25 205 215
-		25,921,573		25,583,998		25,880,554		25,205,215
Weighted average number of shares of common stock outstanding, diluted		27,090,060		25,583,998		25,880,554		25,205,215

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

# HARROW HEALTH, INC. UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY For the Three and Nine Months Ended September 30, 2020 and 2019 (In thousands, except for share data)

	Common	Stools	Additional		Total Harrow Health, Inc.	Total	Total
	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity	Noncontrolling Interest	Stockholders' Equity
Balance at June 30, 2019	25,138,958	\$ 25	\$ 100,271	\$ (65,231)	\$ 35,065	\$ (67)	\$ 34,998
Issuance of common stock in							
connection with: Exercise of warrants	25 125						
Exercise of employee stock-	25,135	-	-	-	-	-	-
based options, net of tax withholding	4,748	-	(44)	-	(44)	-	(44)
Stock-based payment for	,						
services provided	-	-	75	-	75	-	75
Stock-based compensation expense	-	-	328	-	328	-	328
Net loss				(11,469)	(11,469)	(161)	(11,630)
Balance at September 30, 2019	25,168,841	<u>\$ 25</u>	\$ 100,630	\$ (76,700)	\$ 23,955	<u>\$ (228)</u>	\$ 23,727
	C	0. 1	Additional		Total Harrow	Total	Total
	Common	Par	Paid-in	A	Health, Inc. Stockholders'		Stockholders'
	Shares	Value	Capital	Accumulated Deficit	Equity	Noncontrolling Interest	
Balance at June 30, 2020	25,649,171	\$ 26	\$ 102,889	\$ (87,187)	\$ 15,728	\$ (332)	Equity \$ 15,396
	,,	÷ _•	+,,	¢ (0,,,,,)	• •••••	+ ()	+
Issuance of common stock in connection with: Exercise of employee stock-							
based options, net of tax							
withholding	2,998	-	(8)	-	(8)	-	(8)
Stock-based compensation expense	-	-	917	-	917	-	917
Net income (loss)	-	-	-	8,638	8,638	(15)	8,623
Balance at September 30, 2020	25,652,169	\$ 26	\$ 103,798	\$ (78,549)	\$ 25,275	\$ (347)	\$ 24,928
					Total Harrow		
	Common	n Stock	Additional		Health, Inc.	Total	Total
		Par	Paid-in	Accumulated	Stockholders'	Noncontrolling	Stockholders'
	Shares	Value	Capital	Deficit	Equity	Interest	Equity
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	788,528	1	178	-	179	-	179
Exercise of employee stock- based options, net of tax							
withholding	25,703	-	(44)	-	(44)	-	(44)
Stock-based payment for	15 000		150		150		150
services provided Stock-based compensation expense	15,000	-	150 1,408	-	150 1,408	-	150 1,408
Net loss		_	1,400	(2,489)	(2,489)	(228)	(2,717)
Balance at September 30, 2019	25,168,841	\$ 25	\$ 100,630	\$ (76,700)	\$ 23,955	\$ (228)	\$ 23,727
					Total Harrow		
	Common		Additional		Health, Inc.	Total	Total
		Par	Paid-in	Accumulated	Stockholders'	Noncontrolling	Stockholders'
	Shares	Value	Capital	Deficit	Equity	Interest	Equity
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:							

connection with: Exercise of employee stock-

based options, net of tax withholding

-

(8)

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3,251

(8)

(8)

Vesting of RSUs	91,987	-		-	-	-	-	-
Stock-based payment for								
services provided	30,000	-		83	-	83	-	83
Stock-based compensation expense	-	-	1,9	995	-	1,995	-	1,995
Net loss	-	-		-	(4,506)	(4,506)	(54)	(4,560)
Balance at September 30, 2020	25,652,169	\$ 26	\$ 103,7	798 \$	6 (78,549)	\$ 25,275	\$ (347)	\$ 24,928

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)

		1		
		Septem 2020	ioer 50,	2019
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss (including noncontrolling interests)	\$	(4,560)	\$	(2,717)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization of property, plant and equipment		1,377		1,365
Amortization of intangible assets		127		175
Amortization of operating lease right-of-use assets		550		386
Amortization of debt issuance costs and discount		354		394
Provision for bad debt expense		221		-
Investment gain from Eton, net		(2,450)		(700)
Investment loss from Surface, net		1,694		904
Investment loss (gain) from Melt, net		1,536		(4,517)
Loss on sale and disposal of equipment		5		-
Interest paid-in-kind on loan payable		348		-
Impairment of long-lived assets		363		4,013
Stock-based payment of consulting services		83		150
Stock-based compensation		1,995		1,408
Changes in assets and liabilities:		(105)		(001)
Accounts receivable, net of provision for bad debt expense		(407)		(901)
Inventories		(673)		(1,413)
Prepaid expenses and other current assets		(123)		(528)
Accounts payable and accrued expenses		(2,555)		1,721
Accrued payroll and related liabilities		1,575		(371)
Deferred revenue and customer deposits		6		(71)
NET CASH USED IN OPERATING ACTIVITIES		(534)		(702)
CASH FLOWS FROM INVESTING ACTIVITIES				
Proceeds on sale and disposal of assets		-		4
Investment in patent and trademark assets		(111)		(279)
Purchases of property, plant and equipment		(780)		(589)
NET CASH USED IN INVESTING ACTIVITIES		(891)		(864)
CASH FLOWS FROM FINANCING ACTIVITIES				
Payments on finance lease obligations		(6)		(744)
Proceeds from SWK debt		1,000		-
Principal payments on loan payable		(750)		(750)
Payments of costs related to amendment of note payable		-		(282)
Net proceeds from Payroll Protection Program loan payable		1,967		-
Net proceeds from exercise of warrants and stock options, net of taxes remitted for RSU				
and options		(8)		135
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES		2,203		(1,641)
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH		778		(3,207)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period		4,949		6,838
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	¢		¢	
	\$	5,727	\$	3,631
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH	<b>^</b>		<i>•</i>	2 (2)
Cash and cash equivalents	\$	5,527	\$	3,431
Restricted cash		200		200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	\$	5,727	\$	3,631
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Cash paid for income taxes	\$	-	\$	11
Cash paid for interest	\$	1,222	\$	1,546
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING	ψ	1,222	Ψ	1,540
ACTIVITIES:				
New and revaluation of right-of-use asset obtained in exchange for lease obligation	¢	026	¢	
ten and retaindation of tight of use asset obtained in exchange for rease obligation	\$	936	\$	-

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 and nine months ended September 30, 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 Ophthalmics, 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") and Stowe Pharmaceuticals, Inc. ("Stowe"), among others. 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 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 and nine months ended September 30, 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 September 30, 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 September 30, 2020 and December 31, 2019 and the condensed consolidated statements of operations, stockholders' equity and cash flows for the periods ended September 30, 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 may in the future 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 filing 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 and information in the Company's other filings with the Securities and Exchange Commission.

During certain periods, including those impacted by the COVID-19 pandemic, the Company has incurred operating losses and negative cash flows from operations. The Company incurred operating losses of \$2,241 and \$5,721 for the nine months ended September 30, 2020 and 2019, respectively, and had an accumulated deficit of \$78,549 and \$74,043 as of September 30, 2020 and December 31, 2019, respectively. In addition, the Company used cash in operating activities of \$534 and \$702 for the nine months ended September 30, 2020 and 2019, respectively.

While there is no assurance, management of the Company believes existing cash resources and restricted cash of \$5,727 at September 30, 2020 together with cash generated from revenues, will be sufficient to sustain the Company's planned level of operations for at least the next twelve months. However, estimates of operating expenses, working capital requirements and the future impact of the COVID-19 pandemic on its business 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 and nine months ended September 30, 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, restricted stock units ("RSUs") 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 stock options, unvested RSUs and warrants were 5,447,716 and 5,263,131 at September 30, 2020 and 2019, respectively, and, except for the three months ended September 30, 2020, 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 September 30, 2020 and 2019 was 281,507 and 314,588, respectively.

The following table shows the computation of basic net income (loss) per share of common stock for the three and nine months ended September 30, 2020 and 2019:

		For the Three Months Ended September 30,			For the Nine Months Ended September 30,			
	_	2020		2019		2020		2019
Numerator – net income (loss) attributable to Harrow Health, Inc.	\$	8.638	\$	(11,469)	\$	(4,506)	\$	(2,489)
Denominator – weighted average number of shares outstanding, basic	-	25,921,573	-	25,583,998		25,880,554	<u> </u>	25,205,215
Net income (loss) per share, basic	\$	0.33	\$	(0.45)	\$	(0.17)	\$	(0.10)

For the three months ended September 30, 2020, 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 the period. Diluted common equivalent shares for the three months ended September 30, 2020, consisted of the following:

	For the Three months Ended
	September 30, 2020
Diluted shares related to:	
Warrants	504,742
Stock options	663,745
Dilutive common equivalent shares	1,168,487

The following table shows the computation of diluted net income (loss) per share of common stock for the three and nine months ended September 30, 2020 and 2019:

	For the Three Months Ended September 30,				months Ended nber 30,		
		2020		2019	2020		2019
Numerator – net income (loss) attributable to Harrow							
Health, Inc.	\$	8,638	\$	(11,469)	\$ (4,506)	\$	(2,489)
Denominator – weighted average number of shares					 		
outstanding, basic		25,921,573		25,583,998	25,880,554		25,205,215
Dilutive common equivalent shares		1,168,487		-	-		-
Number of shares used for diluted earnings per share							
computation		27,090,060		25,583,998	25,880,554		25,205,215
Net income (loss) per share, diluted	\$	0.32	\$	(0.45)	\$ (0.17)	\$	(0.10)

# Investment in Eton Pharmaceuticals, Inc. - Related Party

The Company owns 3,500,000 shares of Eton common stock, which represents approximately 16.7% of the equity and voting interests of Eton as of September 30, 2020. At September 30, 2020 the fair market value of Eton's common stock was \$7.90 per share. In accordance with Accounting Standard's Update ("ASU") 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, for the three and nine months ended September 30, 2020, the Company recorded an investment gain (loss) from its Eton common stock position of \$8,575 and \$2,450, respectively, related to the change in fair market value of the Company's investment in Eton during the measurement periods. As of September 30, 2020, the fair market value of the Company's investment in Eton was \$27,650.

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 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 of Melt (which is approximately 44% of the equity interests as of September 30, 2020) 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. The Company recorded equity in the net loss of Melt of \$300 and \$1,536 during the three and nine months ended September 30, 2020, respectively. The Company recorded equity in the net loss of Melt of \$682 and \$1,293 during the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, the carrying value of the Company's investment in Melt was \$2,432.

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

# Investment in Surface Ophthalmics, Inc. - Related Party

The Company owns 3,500,000 common shares (which is approximately 30% of the equity interests as of September 30, 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 loss of Surface of \$756 and \$1,694 during the three and nine months ended September 30, 2020, respectively. The Company recorded equity in the net loss of Surface of \$400 and \$904 during the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, the carrying value of the Company's investment in Surface was \$2,053.

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. 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 is currently assessing the impact of this standard and 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.

## **Commission Revenues**

During the third quarter of 2020, the Company entered into an agreement whereby it is paid a fee calculated based on sales it generates from a pharmaceutical product that is owned by a third party. The revenue earned from this arrangement is recognized at the time a customer has ordered the pharmaceutical product and it has shipped from the third party (or one of its distributors or affiliates), at which point there is no future performance obligation required by the Company and no consequential continuing involvement on the part of the Company to recognize the associated revenue.

# Intellectual Property License Revenues

The Company currently holds five intellectual property license and related agreements in which the Company has sold or granted a license which provides a customer with the right to access the Company's intellectual property. License arrangements may include or require 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 and nine months ended September 30, 2020 and 2019, consists of the following:

	For the Three Months Ended September 30,			_	For the Nine Septen		
	2020		2019		2020	2019	
Product sales, net	\$ 14,385	\$	12,748	\$	34,244	\$ 38,540	
Commissions	7		-		7	-	
License	7		7		25	21	
Total revenues	\$ 14,399	\$	12,755	\$	34,276	\$ 38,561	

Deferred revenue and customer deposits at September 30, 2020 and December 31, 2019, was \$63 and \$57, respectively. All deferred revenue and customer deposit amounts at December 31, 2019 were recognized as revenue during the nine months ended September 30, 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 September 30, 2020, the Company was due \$815 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 and nine months ended September 30, 2020, Melt did not make any payments to the Company.

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:

	Nine	For the Months Ended
		mber 30, 2020
Revenues, net	\$	-
Loss from operations		3,261
Net loss	\$	(3,261)

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

	-	mber 30, 020
Current assets	\$	4,072
Non current assets		12
Total assets	\$	4,084
Total liabilities	\$	1,452
Total preferred stock and stockholders' equity		2,632
Total liabilities and stockholders' equity	\$	4,084

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

The Company entered into an asset purchase and license agreement with Surface in 2017, and amended it in April 2018 (the "Surface License Agreements"). 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.

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
	Ni	ne Months Ended
	Se	ptember 30, 2020
Revenues, net	\$	-
Loss from operations		5,647
Net loss	\$	(5,647)

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

	-	ember 30, 2020
Current assets	\$	11,547
Non current assets		45
Total assets	\$	11,592
Total liabilities	\$	1,754
Total stockholders' equity		9,838
Total liabilities and stockholders' equity	\$	11,592

# 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 September 30, 2020 and December 31, 2019 was as follows:

		September 30,		ecember 31,
	2	2020		2019
Raw materials	\$	2,838	\$	2,405
Work in progress		4		20
Finished goods		1,132		876
Total inventories	\$	3,974	\$	3,301

# NOTE 7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	September 30, 2020			December 31, 2019		
Prepaid insurance	\$	149	\$	123		
Other prepaid expenses		378		358		
Receivable due from Melt		815		722		
Deposits and other current assets		89		105		
Total prepaid expenses and other current assets	\$	1,431	\$	1,308		

# NOTE 8. PROPERTY, PLANT AND EQUIPMENT

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

	September 30, 2020			December 31, 2019		
Property, plant and equipment, net:						
Computer software and hardware	\$	1,902	\$	1,732		
Furniture and equipment		463		363		
Lab and pharmacy equipment		3,464		3,164		
Leasehold improvements		5,720		5,510		
		11,549		10,769		
Accumulated depreciation and amortization		(6,776)		(5,394)		
	\$	4,773	\$	5,375		

For the three and nine months ended September 30, 2020, depreciation and amortization related to the property, plant and equipment was \$464 and \$1,377, respectively. For the three and nine months ended September 30, 2019, depreciation related to the property, plant and equipment was \$397 and \$1,365, respectively. During the three and nine months ended September 30, 2019, the Company impaired \$445 of property, plant and equipment related to the Park Restructuring.

# NOTE 9. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at September 30, 2020 consisted of the following:

	Amortization							
	periods		A	ccumulated				Net
	(in years)	Cost	ar	nortization	Im	pairment	Car	rying value
Patents	17-19 years	\$ 911	\$	(86)	\$	(363)	\$	462
Licenses	20 years	50		(6)		-		44
Trademarks	Indefinite	353		-		-		353
Customer relationships	3-15 years	1,519		(421)		-		1,098
Trade name	5 years	5		(5)		-		-
Non-competition								
clause	3-4 years	50		(50)		-		-
State pharmacy								
licenses	25 years	8		(7)		-		1
		\$ 2,896	\$	(575)	\$	(363)	\$	1,958

During the nine months ended September 30, 2020, the Company recorded impairment charges of \$363 related to patent filings associated with products that the Company was no longer actively selling.

Amortization expense for intangible assets for the three and nine months ended September 30, 2020 and 2019 was as follows:

	For Three Mor Septem		For Nine Mon Septerr	
	2020	2019	 2020	2019
Patents	\$ 6	\$ 22	\$ 25	\$ 37
Licenses	-	-	1	5
Customer relationships	33	26	101	128
Trade name	-	1	-	1
State pharmacy licenses	-	3	-	4
	\$ 39	\$ 52	\$ 127	\$ 175

Estimated future amortization expense for the Company's intangible assets at September 30, 2020 is as follows:

Remainder of 2020	\$ 47
2021	173
2022	173
2023	173
2024	146
Thereafter	893
	\$ 1,605

There have been no changes in the carrying value of the Company's goodwill during the three and nine months ended September 30, 2020.

# NOTE 10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	September 30, 2020		December 31, 2019	
Accounts payable	\$	5,511	\$	7,409
Other accrued expenses		-		49
Accrued interest		180		244
Accrued exit fee for note payable		800		800
Total accounts payable and accrued expenses		6,491		8,502
Less: Current portion		(5,691)		(7,702)
Non-current total accrued expenses	\$	800	\$	800

# 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 below). 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 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.

## 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 \$1,000;
- 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 accrued as of such date.

#### 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 has used 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 apply for and subsequently obtain forgiveness of the PPP Loan in whole or in part.

At September 30, 2020, future minimum payments under the Company's debt agreements were as follows:

	A	Amount	
Remainder of 2020	\$	1,299	
2021		5,430	
2022		4,437	
2023		9,669	
Total minimum payments		20,835	
Less: amount representing estimated interest		(3,020)	
Loans payable, gross		17,815	
Less: unamortized discount		(905)	
		16,910	
Less: current portion, net of unamortized discount		(3,750)	
Loans payable, net of current portion and unamortized debt discount	\$	13,160	

For the three and nine months ended September 30, 2020, debt discount amortization related to the SWK loan payable was \$111 and \$354, respectively. For the three and nine months ended September 30, 2019, debt discount amortization related to the SWK loan payable was \$127 and \$377, respectively.

# NOTE 12. LEASES

The Company's leases of office and laboratory space under the non-cancelable operating leases listed below. These lease agreements have remaining lease terms between one to four years and contain various clauses for renewal at our option.

- 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 26,400 square feet of lab, warehouse and office space in Ledgewood, New Jersey, that expires in July 2026, with an option to extend the term for two additional five-year periods. This includes an amendment that was made effective July 2020 that extended the term of the original lease and added 1,400 of additional square footage to the lease; 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.



During the three months ended September 30, 2020, the Company terminated its operating lease for 4,500 square feet of office and lab space in Irvine, California that had an expiration date in December 2020. In connection with the termination, the Company recorded a gain of \$4 which was recognized in other income (expense) on the condensed consolidated financial statements.

At September 30, 2020, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 6.33% and 11.38 years, respectively.

During the three and nine months ended September 30, 2020, cash paid for amounts included for the operating lease liabilities was \$258 and \$805, respectively, and the Company recorded operating lease expense of \$261 and \$816, respectively, included in selling, general and administrative expenses.

Future lease payments under operating leases as of September 30, 2020 were as follows:

	Operation	ng Leases
Remainder of 2020	\$	250
2021		1,017
2022		1,038
2023		1,064
2024		1,090
Thereafter		6,056
Total minimum lease payments		10,515
Less: amount representing interest payments		(3,156)
Total operating lease liabilities		7,359
Less: current portion, operating lease liabilities		(579)
Operating lease liabilities, net of current portion	\$	6,780

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

Future lease payments under finance leases as of September 30, 2020 were as follows:

	Finance Leases	
Remainder of 2020	\$	2
2021		9
2022		9
2023		9
2024		1
Total minimum lease payments		30
Less: amount representing interest payments		(3)
Present value of future minimum lease payments		27
Less: current portion, finance lease obligation		(7)
Finance lease obligation, net of current portion	\$	20

At September 30, 2020, the incremental borrowing rate and the remaining lease term for the finance lease held by the Company were 6.36% and 3.33 years, respectively.

For the three and nine months ended September 30, 2020, depreciation expense related to the equipment held under the finance lease obligation was \$2 and \$6, respectively.

For the three and nine months ended September 30, 2020, cash paid and expense recognized for interest expense related to the finance lease obligation was \$0 and \$1, respectively.

# NOTE 13. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

# **Common Stock**

In May 2020, the Company issued 30,000 shares of its restricted common stock, with a fair value of \$167, as consideration for commission expenses incurred during the year ended December 31, 2019 and the nine months ended September 30, 2020.

During the nine months ended September 30, 2020, the Company issued 253 shares of its common stock upon the cashless exercise of 750 options to purchase common stock, with an exercise price of \$3.04 per share, net of 69 shares of common stock withheld for payroll tax withholdings.

During the nine months ended September 30, 2020, the Company issued 2,998 shares of its common stock upon the exercise of 2,998 options to purchase common stock, with exercise prices ranging from \$3.04 to \$3.20 per share, and paid \$8 related to payroll tax withholdings.

During the nine months ended September 30, 2020, the Company issued 91,987 shares of its common stock underlying RSUs held by a director that resigned. The RSUs had previously vested, including 2,429 RSUs during the nine months ended September 30, 2020, but the issuance and delivery of the shares were deferred until the director resigned.

During the nine months ended September 30, 2020, 46,762 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 resignation of a director.

## **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 September 30, 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 342,882 shares available for future issuances under the 2017 Plan at September 30, 2020.



A summary of stock option activity under the Plans for the nine months ended September 30, 2020 is as follows:

	Number of shares	Weighted Avg. Exercise Price		8 8		regate Intrinsic Value
Options outstanding - January 1, 2020	2,656,683	\$	5.30		_	
Options granted	414,500	\$	6.44			
Options exercised	(3,748)	\$	3.06			
Options cancelled/forfeited	(14,369)	\$	17.42			
Options outstanding - September 30, 2020	3,053,066	\$	5.41	5.97	\$	3,608
Options exercisable – September 30, 2020	1,855,150	\$	4.45	5.38	\$	3,294
Options vested and expected to vest – September 30, 2020	2,940,527	\$	5.34	5.93	\$	3,605

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 September 30, 2020, based on the closing price of the Company's common stock of \$5.59 on that date.

During the nine months ended September 30, 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 nine months ended September 30, 2020 generally 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 Plans) and in the event of certain modifications to the option award agreement.

On July 31, 2015, the Company granted to its Chief Executive Officer, Mark Baum, an option (the "Baum Performance Option") to purchase 600,000 shares of the Company's common stock at an exercise price of \$7.87 per share under the 2007 Plan subject to the satisfaction of certain market-based vesting criteria. The market-based vesting criteria are separated into five tranches and require that the Company achieve and maintain certain average stock price targets ranging from \$9 per share to \$15 per share during the five year period following the grant date. On June 4, 2020, the Company amended the Baum Performance Option, to extend the vesting and contractual term by 5 years. The Company treated this amendment as a modification to the Baum Performance Option for accounting purposes. The fair value of the modification was \$1,876 using a Monte Carlo Simulation with a five year life, 70% volatility and a risk-free interest rate of 0.40%.

With the exception of the Baum Performance Option, 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:

	20	020
Weighted-average fair value of options granted	\$	3.86
Expected terms (in years)		0.5 - 6.11
Expected volatility	66.5	% - 71.4%
Risk-free interest rate	0.34	% - 1.64%
Dividend vield		-

The following table summarizes information about stock options outstanding and exercisable at September 30, 2020:

	Options Outstanding				Options Exercisable		
		Weighted					
		Average		Weighted			Weighted
		Remaining Average				Average	
	Number	Contractual		Exercise	Number		Exercise
Range of Exercise Prices	Outstanding	Life in Years		Price	Exercisable		Price
\$1.47 - \$2.60	778,690	5.90	\$	2.05	728,938	\$	2.07
\$2.76 - \$4.66	531,785	5.95	\$	3.98	453,157	\$	3.98
\$5.49 - \$6.36	496,350	7.47	\$	6.10	263,814	\$	6.12
\$6.64 - \$8.99	1,246,241	5.42	\$	7.85	409,241	\$	8.13
\$1.47 - \$8.99	3,053,066	5.97	\$	5.41	1,855,150	\$	4.45

As of September 30, 2020, there was approximately \$6,021 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 4.03 years. The stock-based compensation expense for all stock options was \$559 and \$1,094 during the three and nine months ended September 30, 2020, respectively.

# 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.

During the nine months ended September 30, 2020, the Company's board of directors were granted 68,024 RSUs with a fair market value \$400 which vest on a quarterly basis, over one year in equal installments.

During the nine months ended September 30, 2020, the Company granted 10,000 RSUs to a new member of its board of directors, with a fair market value of \$39 which vest on the one-year anniversary of the grant date.

During the three and nine months ended September 30, 2020, the Company granted 12,500 RSUs to a new member of its board of directors, with a fair market value of \$72 which vest on the one-year anniversary of the grant date.

During the nine months ended September 30, 2020, 161,000 RSUs with a fair market value of \$1,025 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.



A summary of the Company's RSU activity and related information for the nine months ended September 30, 2020 is as follows:

		eighted Average Frant Date Fair
	Number of RSUs	Value
RSUs unvested - January 1, 2020	1,411,930	\$ 2.76
RSUs granted	251,524	\$ 6.11
RSUs vested	(49,190)	\$ 6.61
RSUs cancelled/forfeited	-	
RSUs unvested at September 30, 2020	1,614,264	\$ 3.16

As of September 30, 2020, the total unrecognized compensation expense related to unvested RSUs was approximately \$1,610, which is expected to be recognized over a weighted-average period of 0.42 years, based on estimated and actual vesting schedules of the applicable RSUs. The stock-based compensation for RSUs during the three and nine months ended September 30, 2020 was \$357 and \$884, 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 nonemployees for services rendered or to be rendered in the future, or pursuant to settlement agreements.

A summary of warrant activity for the nine months ended September 30, 2020 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted Avg. Exercise Price		
Warrants outstanding - January 1, 2020	780,386	\$	2.12	
Granted	-			
Exercised	-			
Expired	-			
Warrants outstanding and exercisable - September 30, 2020	780,386	\$	2.12	
Weighted average remaining contractual life of the outstanding warrants in years - September 30, 2020	3.78			

Warrants outstanding and exercisable as of September 30, 2020 are as follows:

		Warrants	Exercise	Expiration
Warrant Series	Issue Date	Outstanding	 Price	Date
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
		780,386	\$ 2.12	

# Subsidiary Stock-Based Transactions

# Mayfield Pharmaceuticals, Inc.

During the nine months ended September 30, 2020, Mayfield repurchased 650,000 shares of its common stock from Elle, for an aggregate purchase price of \$1.

During the nine months ended September 30, 2020, Mayfield issued 475,000 shares of its restricted common stock, with a fair value of \$11, that vest upon various performance-based milestones and over a four-year service period to Mayfield's Chief Executive Officer candidate. During the nine months ended September 30, 2020, the Company recognized \$17 in stock-based compensation tied to the Mayfield stock options.

During the nine months ended September 30, 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				For the Nine Months Ended			
				Septem	eptember 30, 2020 September 30, 2019			
Employees - selling, general and administrative	\$	740	\$	252	\$	1,612	\$	1,158
Directors - selling, general and administrative		177		75		370		225
Consultants - selling, general and administrative		-		76		96		175
Total	\$	917	\$	403	\$	2,078	\$	1,558

# 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. On October 29, 2020, at a hearing on the various dispositive motions before it, the Court found that there were triable issues of fact and reopened discovery for limited purposes. 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 thirdparty 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 the Company 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 and the Company's motion for summary adjudication is pending before the Court. 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% to 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 \$0 and \$55 were made during the three and nine months ended September 30, 2020, respectively. Royalty expense of \$38 and \$94 was incurred during the three and nine months ended in accounts payable and is due to Dr. Lindstrom at September 30, 2020.

# 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 \$0 and \$7 in cash during the three and nine months ended September 30, 2020, respectively, and an additional \$48 was payable to Dr. Lindstrom at September 30, 2020. The Company incurred royalty expense of \$6 and \$48 related to the Lindstrom APA during the three and nine months ended September 30, 2020, respectively.

# **Eyepoint Commercial Alliance Agreement**

In August 2020, the Company, through its wholly-owned subsidiary ImprimisRx, LLC, entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted the Company the non-exclusive right to co-promote  $DEXYCU^{(R)}$  (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint will pay the Company a fee calculated based on the quarterly sales of DEXCYU in excess of predefined volumes to specific customers of the Company in the U.S. Under the terms of the Dexycu Agreement, the Company shall use commercially reasonable efforts to promote and market DEXCYU in the U.S.

Subject to early termination, the Dexycu Agreement expires on August 1, 2025, subject to specified notice periods and specified limitations, either party may terminate the Dexycu Agreement in the event of (i) uncured material breach by the other party or (ii) if DEXCYU ceases to have "pass-through" payment status. In addition, subject to certain limitations, the Company may terminate the Dexycu Agreement (i) for convenience subject to an extended specified notice period or (ii) in the event Eyepoint undergoes a change of control. Eyepoint may terminate the Dexycu Agreement, subject to specified notice periods and specified limitations, if the Company fails to achieve certain minimum sales levels during specified periods. During the three and nine months ended September 30, 2020, the Company recorded \$7 in commission revenues related to the Dexycu Agreement.

# 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% to 14% of net sales for products above and beyond the initial existing sales amounts. In addition, the Company is required to issue shares of the Company's restricted common stock to certain organizations if net sales in the assigned territory reach certain future milestone levels by the end of their terms, as applicable. Commission expenses of \$741 and \$1,745 were incurred under these agreements during the three and nine months ended September 30, 2020, respectively, of which \$0 and \$83 were stock-based payments.



# 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 U.S. Food and Drug Administration ("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 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. Royalty expenses of \$159 and \$420 and \$207 are included in accounts payable at September 30, 2020 and 2019, respectively, and \$590 and \$207 are included in accounts payable at September 30, 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 the ImprimisRx business; 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 and nine months ended September 30, 2020:

	For the Three Months Ended September 30, 2020						
		maceutical		aceutical velopment		Total	
Net revenues	\$	14,399	\$	-	\$	14,399	
Cost of sales		(3,696)		-		(3,696)	
Gross profit		10,703		-		10,703	
Operating expenses:							
Selling, general and administrative		5,893		44		5,937	
Research and development		94		22		116	
Segment contribution	\$	4,716	\$	(66)		4,650	
Corporate						2,460	
Research and development						554	
Amortization						39	
Asset sales and impairments, net						-	
Operating income					\$	1,597	

Pharmaceutical Compounding 34,276 (10,526) 23,750	Pharmaceutical Drug Development \$ - -	Total \$ 34,276 (10,526) 23,750
(10,526)	\$ 	(10,526)
23,750	-	23,750
17,131	131	17,262
634	79	713
5,985	\$ (210)	5,775
		6,417
		1,109
		127
		363
		\$ (2,241)
	634	634 79



	For the Three Months Ended September 30, 2019							
		maceutical		aceutical velopment		Total		
Net revenues	\$	12,755	\$	-	\$	12,755		
Cost of sales		(4,061)		-		(4,061)		
Gross profit		8,694		-		8,694		
Operating expenses:								
Selling, general and administrative		6,244		44		6,288		
Research and development		193		96		289		
Segment contribution	\$	2,257	\$	(140)		2,117		
Corporate						2,280		
Research and development						155		
Amortization						40		
Asset sales and impairments, net						4,040		
Operating loss					\$	(4,398)		

	For the Nine Months Ended September 30, 2019						
		maceutical		aceutical evelopment		Total	
Net revenues	\$	38,561	\$	-	\$	38,561	
Cost of sales		(13,184)		-		(13,184)	
Gross profit		25,377		-		25,377	
Operating expenses:							
Selling, general and administrative		17,763		130		17,893	
Research and development		851		359	_	1,210	
Segment contribution	\$	6,763	\$	(489)		6,274	
Corporate						7,341	
Research and development						449	
Amortization						165	
Asset sales and impairments, net					_	4,040	
Operating loss					\$	(5,721)	

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 September 30, 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 and nine months ended September 30, 2020 and 2019.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 76% and 72% of active pharmaceutical ingredient purchases during the three and nine months ended September 30, 2020, respectively, and 69% and 66% during the three and nine months ended September 30, 2019, respectively.

# NOTE 16. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to September 30, 2020 through the filing date of this Quarterly Report. Based on its evaluation, no events other than those described herein need to be disclosed.

In October 2020, the Company issued 93,798 shares of its common stock underlying RSUs held by a director that resigned. The RSUs had previously vested during the nine months ended September 30, 2020, but the issuance and delivery of the shares were deferred until the director resigned.

## 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 and in our other filings with the Securities and Exchange Commission. 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 and operate one of the nation's leading ophthalmology pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, we also have non-controlling equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Ophthalmics, 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") and Stowe Pharmaceuticals, Inc. ("Stowe"), among others. We also intend to launch a new business called Visionology. We own royalty rights in various drug candidates being developed by Surface, Melt 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 prescription pharmaceutical business. We offer to over 9,000 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 FDA guidance documents, in our FDA-registered New Jersey Outsourcing Facility ("NJOF").

# 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 within a certain region of the U.S after securing financing. If successful, Visionology will expand the launch on a nationwide basis later in 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 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, and Stowe 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. 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 inlicense/acquire and/or otherwise develop.

## **Consolidated Businesses (Controlling Equity Interests)**

#### 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. In October 2020, we completed in vivo preclinical studies of certain anti-viral activity of STE-006 along with another asset DS-007. We also conducted in vitro studies earlier in the year, that studied certain antibacterial activity of STE-006. While the initial data from our studies were positive, we were unable to replicate as strong of data as previously produced on STE-006. Therefore, while we remain interested in pathogen-agnostic topical agents to treat non-specific conjunctivitis, we do not intend to invest further in STE-006. We are currently evaluating the market and clinical potential of DS-007 and other Harrow formulations in the anti-infective category.

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 September 30, 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 September 30, 2020. We are currently pursuing a deconsolidating transaction for Mayfield. We have contracted with an experienced life science executive that we expect to lead Mayfield once deconsolidated.

#### Radley Pharmaceuticals, Inc.

Radley Pharmaceuticals, Inc. ("Radley"), a consolidated subsidiary of Harrow, is a development-stage pharmaceutical company that has been focused on the development of proprietary drug candidates focused on rare diseases. Radley currently has three drug programs in its pipeline. During the second quarter of 2020, we suspended all activities related to Radley to focus attention and capital on other projects. Currently, we do not intend to resume the activities related to Radley.



## **De-Consolidated Businesses (Noncontrolling Equity Interests)**

#### 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 September 30, 2020.

# Surface Ophthalmics, Inc. (f/k/a 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 were delayed as a result of the ongoing COVID-19 pandemic and as a result, data from these clinical programs will likely be delayed as well.

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 September 30, 2020. We expect Surface to complete another round of financing within the next twelve months.

#### 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 filed an IND in June 2020 and has begun its clinical program for MELT-100. We expect Melt will announce topline data from its Phase 1 study during the fourth quarter of 2020 or first quarter of 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 September 30, 2020. We expect Melt to complete another round of financing within the next twelve months.

# **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 conceivable 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-payor 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 have previously made 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. In September 2020, we were informed by CMS that our application for pass-through payment was denied for one of our formulations. Any future efforts to attain optimized pricing or reimbursement of our other proprietary compounded 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 as well as operating trends and prospects. 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 that were 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, the reduction in elective procedures in response to CMS guidance has had a material adverse impact, on our revenues, profitability and cash flows, in particular during the second quarter of 2020. The extent and duration of future impact will depend upon the extent of procedure postponements, the duration of the pandemic and any resurgences of it, especially within certain geographies and states that have retained restrictive measures and social distancing policies. In May 2020 and the following months, some U.S. states and geographies began easing restrictions associated with the COVID-19 pandemic including those restrictions related to elective procedures, as restrictions were lifted in those areas there was a correlation with an increase in our revenues. Despite the recent resurgence of the COVID-19 pandemic in certain parts of the U.S., we are hopeful that the general trend of easing of restrictions will continue, and sales of our products will return to historical norms and historical growth trends, as other states and governmental authorities continue to 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 the PPP Loan with Renasant Bank in the principal amount of \$1,967,100 and received cash proceeds of the same amount, pursuant to the PPP under the CARES Act, which was enacted March 27, 2020. The PPP is administered by the U.S. Small Business Administration (the "SBA").

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 we used 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 apply for or obtain forgiveness of the PPP Loan in whole or in part.

## Eyepoint Commercial Alliance Agreement

On August 1, 2020, our wholly-owned subsidiary ImprimisRx entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted ImprimisRx the non-exclusive right to co-promote DEXYCU<sup>®</sup> (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint will pay ImprimisRx a fee calculated based on the quarterly sales of DEXCYU in excess of predefined volumes to specific customers of ImprimisRx in the U.S. Under the terms of the Dexycu Agreement, ImprimisRx shall use commercially reasonable efforts to promote and market DEXCYU in the U.S.

Subject to early termination, the Dexycu Agreement expires on August 1, 2025. Subject to specified notice periods and specified limitations, either party may terminate the Dexycu Agreement in the event of (i) uncured material breach by the other party or (ii) if DEXCYU ceases to have "pass-through" payment status. In addition, subject to certain limitations, ImprimisRx may terminate the Dexycu Agreement (i) for convenience subject to an extended specified notice period or (ii) in the event Eyepoint undergoes a change of control. Eyepoint may terminate the Dexycu Agreement, subject to specified notice periods and specified limitations, if ImprimisRx fails to achieve certain minimum sales levels during specified periods.

## **Results of Operations**

The following period-to-period comparisons of our financial results for the three and nine months ended September 30, 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 and nine months ended September 30, 2020 and 2019:

	For the Three Months Ended September 30,					For the Nine Months Ended September 30, \$					\$
		2020		2019	Variance		2020		2019		Variance
Product sales, net	\$	14,385,000	\$	12,748,000	\$ 1,637,000	\$	34,244,000	\$	38,540,000	\$	(4,296,000)
Other revenues	_	14,000		7,000	 7,000		32,000		21,000		11,000
Total revenues	\$	14,399,000	\$	12,755,000	\$ 1,644,000	\$	34,276,000	\$	38,561,000	\$	(4,285,000)

The increase in revenues between the three months ended September 30, 2020 and the same period in the prior year was largely attributable to an increase in customer demand and unit volumes sold. The decrease in revenues between the nine months ended September 30, 2020 and the same period in the prior year was largely attributed to the COVID-19 pandemic and CMS guidance to limit elective procedures during parts of the first and second quarters of 2020. Net revenues generated from NJOF totaled \$10,205,000 and \$23,010,000 during the three and nine months ended September 30, 2020, and \$8,860,000 and \$24,102,000 during the three and nine months ended September 30, 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 and nine months ended September 30, 2020 and 2019:

	For the Three Months Ended				For the Nine Months Ended							
	September 30,				\$		September 30,			\$		
	 2020	2019			Variance		2020		2019		Variance	
Cost of sales	\$ 3,696,000	\$	4,061,000	\$	(365,000)	\$	10,526,000	\$	13,184,000	\$	(2,658,000)	

The decrease in our cost of sales between the three months ended September 30, 2020 and the same period in the prior year was largely attributable to increased efficiencies and the August 2019 closure of our Irvine, California based pharmacy. The decrease in cost of goods sold between the nine months ended September 30, 2020 and the same period in the prior year was largely due to a decrease in unit volumes sold impacted by the COVID-19 pandemic, partially offset by continued improved utilization of capacity at our compounding facilities.

## Gross Profit and Margin

	For the Three Months Ended September 30,				For the Nine Months Ended\$September 30,						\$		
		2020		2019	) Varia			2020 2019		2019	Variance		
Gross Profit	\$	10,703,000	\$	8,694,000	\$	2,009,000	\$	23,750,000	\$	25,377,000	\$	(1,627,000)	
Gross Margin	_	74%	_	68%	_	6%	_	69%	_	66%	_	3%	

Increased efficiencies in our production process, extension of beyond using dating, or BUD, of some of our products, the closure of our Irvine, California based pharmacy in August 2019 and an increase in sales prices has contributed to our gross margin increase.

## 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 and nine months ended September 30, 2020 and 2019:

	For the Three Months Ended September 30,			\$	For the Nine Months Ended September 30,				\$	
	2020	_	2019	 Variance		2020		2019		Variance
Selling, general and administrative	\$ 8,436,000	\$	8,608,000	\$ (172,000)	\$	23,806,000	\$	25,399,000	\$	(1,593,000)

The decrease in selling, general and administrative expenses between periods was largely attributable to decreased legal expenses incurred associated with certain litigation matters that concluded during 2019, and certain expenses that are correlated with our sales.

#### Research and Development Expenses

Our research and development expenses primarily include expenses related to the development of acquired intellectual property, investigatorinitiated 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 and nine months ended September 30, 2020 and 2019:

	For the Three Months Ended September 30,			\$	For the Nine Septem	\$		
	 2020		2019	Variance	2020	2019	V	ariance
Research and development	\$ 670,000	\$	444,000	\$ 226,000	\$ 1,822,000	\$ 1,659,000	\$	163,000
				37				

The increase in 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 and nine months ended September 30, 2020.

## Interest Expense, net

Interest expense, net was \$498,000 and \$1,563,000 for the three and nine months ended September 30, 2020, compared to \$620,000 and \$1,939,000 for the same respective periods last year. The decrease during the period ended September 30, 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 and nine months ended September 30, 2020, we recorded a loss of \$300,000 and \$1,536,000, respectively, for our share of losses based on our ownership of Melt. During the nine months ended September 30, 2019, we recorded a net gain of \$4,517,000 related to our investment in Melt. We recorded a gain of \$5,810,000 for the deconsolidation of Melt, and a loss of \$1,293,000 for our share of losses based on our ownership of Melt. We began using the 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, Melt's losses were consolidated within our statements of operations.

## Investment Loss from Surface, net

During the three and nine months ended September 30, 2020, we recorded a loss of \$756,000 and \$1,694,000, respectively, for our share of losses based on our ownership of Surface. During the three and nine months ended September 30, 2019, we recorded a loss of \$400,000 and \$904,000, respectively, for our share of losses based on our ownership of Surface. We began using the equity method accounting for our investment in Surface beginning on June 11, 2018, the date we no longer had a controlling interest. Prior to that date, Surface's losses were consolidated within our statements of operations.

#### Investment Gain (Loss) from Eton, net

We recorded a gain of \$8,575,000 and \$2,450,000 related to the change in fair market value of Eton's common stock for the three and nine months ended September 30, 2020, respectively. We recorded a loss of \$(5,530,000) and a gain of \$700,000 related to the change in fair market value of Eton's common stock for the three and nine months ended September 30, 2019, respectively. We began recording our investment in Eton at fair market value and ceased using the equity method accounting for our investment in Eton in November 2018 following Eton's Initial Public Offering and our ownership falling below 20%.

#### Other Income, net

During the nine months ended September 30, 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. During the nine months ended September 30, 2020, we recorded other income, net of \$24,000. This was primarily the result of income of \$19,000 related to equipment from our Park facility that was sold during the nine months ended September 30, 2020.

#### Net Loss

The following table presents our net income (loss) for the three and nine months ended September 30, 2020 and 2019:

	F	For the Three Septem		Ended	For the Nine Months Ended September 30,				
	2020			2019	 2020	201			
Numerator – net income (loss)	\$	8,638	\$	(11,469)	\$ (4,506)	\$	(2,489)		
Net income (loss) per share, basic	\$	0.33	\$	(0.45)	\$ (0.17)	\$	(0.10)		
Net income (loss) per share, diluted	\$	0.32	\$	(0.45)	\$ (0.17)	\$	(0.10)		
					 		i		
			38						

## **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 research and development 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 September 30, 2020 was \$5,727,000, compared to \$4,949,000 at December 31, 2019. Since inception, July 24, 1998, through September 30, 2020, we have incurred aggregate losses of \$78,549,000. 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 discontinued in 2013, 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 \$5,527,000 and restricted cash of \$200,000, totaling approximately \$5,727,000 at September 30, 2020 together with cash generated from revenues, 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 interests 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 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 Nine Months Ended September 30,						
		2020		2019			
Net cash (used in) provided by:							
Operating activities	\$	(534,000)	\$	(702,000)			
Investing activities		(891,000)		(864,000)			
Financing activities		2,203,000		(1,641,000)			
Net change in cash and cash equivalents		778,000	_	(3,207,000)			
Cash, cash equivalents and restricted cash at beginning of the period		4,949,000		6,838,000			
Cash, cash equivalents and restricted cash at end of the period	\$	5,727,000	\$	3,631,000			

#### **Operating** Activities

Net cash used in operating activities was \$(534,000) during the nine months ended September 30, 2020, compared to \$(702,000) in operating activities during the same period in the prior year. The decrease in net cash used in operating activities during the period was mainly attributed to the increase in revenue during the quarter ended September 30, 2020 and increased operational efficiencies.

#### Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2020 and 2019 was \$(891,000) and \$(864,000), 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 provided by (used in) financing activities during the nine months ended September 30, 2020 and 2019 was \$2,203,000 and \$(1,641,000), respectively. Cash provided by financing activities during the nine months ended September 30, 2020 was related to proceeds received from the amendment to our loan and security agreement with SWK as well as proceeds received from the PPP Loan.

#### 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, and during the third quarter of 2020; however, during the second quarter of 2020, we experienced a significant downturn in revenues mostly as a result of the COVID-19 pandemic which may have an impact on our ability to produce cash for 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 any related interim stay-at-home orders and future 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/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 r

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 September 30, 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 September 30, 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 September 30, 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**

See Note 14 to our consolidated condensed financial statements included in tie Quarterly Report for information on various legal proceedings, which is incorporated into this Item by reference.

### 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 Quarterly Report on Form 10-Q for the three months ended September 30, 2020 and 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.

### Our business is significantly impacted by state and federal statutes and regulations.

Our proprietary formulations are comprised of active pharmaceutical ingredients that are components of drugs that have received marketing approval from the FDA, although our proprietary compounded formulations have not themselves received FDA approval. FDA approval is not required in order to market and sell our compounded formulations. In the future we may choose to pursue FDA approval to market and sell certain potential drug candidates. The marketing and sale of compounded formulations is subject to and must comply with extensive state and federal statutes and regulations governing compounding pharmacies. These statutes and regulations include, among other things, restrictions on compounding for office use or in advance of receiving a patient-specific prescription or, for outsourcing facilities, requirements regarding preparation, such as regular FDA inspections and cGMP requirements, prohibitions on compounding drugs that are essentially copies of FDA-approved drugs, limitations on the volume of compounded formulations on wholesaling or reselling. These and other restrictions on the activities of compounding pharmacies and outsourcing facilities may significantly limit the market available for compounded formulations, compared to the market available for FDA-approved drugs.

Our pharmacy business is impacted by federal and state laws and regulations governing the following: the purchase, distribution, management, compounding, dispensing, reimbursement, marketing and labeling of prescription drugs and related services including; FDA and/or state regulation affecting the pharmacy and pharmaceutical industries, including state pharmacy licensure and registration or permit standards; rules and regulations issued pursuant to HIPAA and other state and federal laws related to the use, disclosure and transmission of health information; and state and federal controlled substance laws. Our failure to comply with any of these laws and regulations could severely limit or curtail our pharmacy operations, which would materially harm our business and prospects. Further, our business could be adversely affected by changes in these or any newly enacted laws and regulations, and federal and state agency interpretations of the statutes and regulations. Statutory or regulatory changes could require us to make changes to our business model and operations and/or could require us to incur significantly increased costs to comply with such regulations.

On July 30, 2020, the FDA issued a notice for comments related to certain bulk drug substances to be removed from the 503B Bulk's List (or Category 1 List). Included in this notice for comment were certain bulk drug substances which we currently use in some of our compounded products. In the event one or more of these bulk substances are ultimately removed from the Category 1 List, we intend to utilize commercially available versions of these substances or similar active pharmaceutical ingredients as replacements of the bulk powders contained in our sterile products. In addition, nothing in the FDA's notice affects the dispensing of bulk powder-containing products from our 503A pharmacy. Nonetheless, if all or some of the bulk drug substances we use are removed from the 503B Bulk's List, this may result in a disruption in our operations, revenues and cash flows.



On October 27, 2020, the FDA announced availability of a final Memorandum of Understanding, Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration (the "MOU"). The MOU describes the responsibilities of a state board of pharmacy, or other appropriate state agency that chooses to sign the MOU, in investigating and responding to complaints related to drug products compounded in such state and distributed outside such state and in addressing the interstate distribution of inordinate amounts of compounded human drug products. Additionally, as part of the MOU, FDA refined the definition of "inordinate amount," a threshold for certain information identification and sharing which does not place a limit on the distribution of compounded human drug products interstate by a pharmacy located in a state that has entered into the MOU. Section 503A of the FDCA sets a five percent limit on compounded drugs distributed outside the state by a pharmacist, pharmacy or physician located in a state that has not entered into the MOU.

States have 365 days to sign the MOU, before the FDA intends to enforce the five percent limit described in Section 503A of the FDCA in states that have not signed the MOU. Our pharmacy is based in the state of New Jersey, and we believe the state board of pharmacy in New Jersey will sign the MOU and as a result, our operations will not be materially affected by the MOU. In the event New Jersey does not sign the MOU, our pharmacy that operates under Section 503A may be materially affected and we will transition as many prescription orders as possible to our outsourcing facility, which is not subject to the MOU.

# Our loan under the Paycheck Protection Program may not be forgiven or may subject us to challenges and investigations regarding qualification for the loan.

In April 2020, we received the PPP Loan, which was established under the CARES Act in the principal amount of \$1,967,000. Pursuant to Section 1106 of the CARES Act we may apply for and be granted forgiveness for all or a portion of the PPP Loan. Such forgiveness will be determined, subject to limitations, based on the use of the loan proceeds for qualifying expenses, which include payroll costs, rent, and utility costs over the allowable measurement period following receipt of the loan proceeds.

The SBA continues to develop and issue new and updated guidance regarding the PPP Loan application and forgiveness process, including guidance regarding required borrower certifications and requirements for forgiveness of loans made under the program. Given the evolving nature of the guidance and depending upon our ability to use the loan proceeds for qualifying expenses, we cannot give any assurance that our PPP Loan will be forgiven in whole, in part, or that we will apply for forgiveness.

Additionally, the PPP Loan application required us to certify that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP Loan, including the False Claims Act, we may be subject to penalties, including significant civil, criminal and administrative penalties and would be required to repay the PPP Loan. In the event that we seek forgiveness of all or a portion of the PPP Loan, we will also be required to be inaccurate, including being required to repay the PPP loan. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could materially harm our business, results of operations and financial condition.

## 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
10.1*#	Commercial Alliance Agreement between Eyepoint Pharmaceuticals, Inc. and ImprimisRx, LLC dated August 1, 2020.
31.1*	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.
31.2*	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.
32.1**	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.
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 September 30, 2020, has been formatted in Inline XBRL.

\* Filed herewith.

- \*\* Furnished herewith.
- # Portions of this exhibit have been omitted in compliance with item 601 of Regulation S-K

## 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: November 9, 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)

# Portions of this exhibit indicated by bracketed asterisks have been omitted because they are not material and would likely cause competitive harm to EyePoint Pharmaceuticals, Inc. if publicly disclosed.

## COMMERCIAL ALLIANCE AGREEMENT

THIS COMMERCIAL ALLIANCE AGREEMENT (this "<u>Agreement</u>") effective as of August 1, 2020 (the "<u>Effective Date</u>"), is entered into between EYEPOINT PHARMACEUTICALS, INC., a Delaware corporation ("<u>EyePoint</u>"), having a place of business at 480 Pleasant Street, Suite B300, Watertown, Massachusetts 02472, and IMPRIMISRX, LLC a Delaware limited liability company ("<u>Imprimis</u>" and together with EyePoint, the "<u>Parties</u>" (with each being a "<u>Party</u>")), having a place of business at 12264 El Camino Real, Suite 350, San Diego, California 92130.

WHEREAS, Imprimis intends to wind down and terminate its operations relating to the manufacture and sale of Tri-moxi (as defined below) and is seeking an alternative product to commercialize in the United States;

WHEREAS, EyePoint owns rights to the product known as Dexycu (as defined below) in the United States and is seeking additional support for its promotional efforts with respect thereto; and

WHEREAS, EyePoint wishes to engage Imprimis to perform, and Imprimis wishes to perform, certain promotional activities for Dexycu in the United States, on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

#### 1. Definitions and Interpretation.

1.1 <u>Definitions</u>. For purposes of this Agreement, the terms defined in this Section 1 have the respective meanings set forth below, and grammatical variations have corresponding meanings:

1.1.1 "<u>Affiliate</u>" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. For the purposes of this definition, a Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever.

1.1.2 "Baseline Demand" means, with respect to a Customer and a period of time, the Baseline Quarterly Amount for such Customer prorated for such period of time.

1.1.3 "<u>Baseline Period</u>" means (a) with respect to the Group A Customers, [\*\*\*](the "<u>Initial Baseline Months</u>"), (b) with respect to the Group B Customers, the period consisting of (i) [\*\*\*] full calendar months immediately following the Effective Date and (ii) [\*\*\*] months of the Initial Baseline Months with the highest Customer Demand for such Customer, and (c) with respect to any other Customer, such other [\*\*\*]period as determined by the Commercialization Committee pursuant to Section 7.1.2.

1.1.4 "Baseline Quarterly Amount" means, with respect to a Customer, the aggregate Customer Demand for such Customer during the applicable Baseline Period *divided* by two (2).

1.1.5 "cGMP" means the principles detailed in the United States Current Good Manufacturing Practices (21 C.F.R. §§200, 211 and 600).

1.1.6 "<u>Change of Control</u>" means, with respect to a Person: (a) any sale, exchange, transfer, or issuance to or acquisition in one transaction or a series of related transactions resulting in a Third Party controlling at least fifty percent (50%) of the ownership interest of such Person, whether such sale, exchange, transfer, issuance or acquisition is made directly or indirectly, by merger or otherwise, or beneficially or of record; (b) a merger or consolidation under applicable law of such Person, with a Third Party in which the shareholders or equity holders of such Person, or any Affiliate that directly or indirectly controls such Person, immediately prior to such merger or consolidation do not continue to control the entity surviving or resulting from such merger or consolidation; or (c) a sale or other disposition of all or substantially all of the assets of such Person to which this Agreement relates, to one or more Third Party(ies) in one transaction or a series of related transactions. For the purposes of this definition, a Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person by any means whatsoever.

7.1.1.

1.1.7 "Commercialization Committee" means the committee comprising representatives of EyePoint and Imprimis described in Section

,....

1.1.8 "<u>Commercially Reasonable Efforts</u>" means, in the case of either Party, with respect to any Product, those efforts and resources that such Party would typically devote to a product owned by it or to which it has rights of the type it has hereunder, which is of similar market potential at a similar stage in its development or product life, taking into account its relative potential safety and efficacy, competitive position, pricing and launching strategy, proprietary position and profitability and other relevant legal, medical, regulatory, scientific or technical factors. Notwithstanding the foregoing, the use of Commercially Reasonable Efforts by a Party with respect to the promotion or marketing, or solicitation of customers for, Products shall require the use of efforts, standards and resources typically devoted by similarly situated companies engaged in the sale of FDA approved pharmaceutical products.

1.1.9 "<u>Confidential Information</u>" means all information and data that (a) is provided by one Party to the other Party or any of its Affiliates under this Agreement, and (b) if disclosed in writing or other tangible medium is marked or identified as confidential at the time of disclosure to the recipient, is acknowledged at the time of disclosure to be confidential, or otherwise should reasonably be deemed to be confidential. Notwithstanding the foregoing, Confidential Information of a Party shall not include that portion of such information and data which, and only to the extent, the recipient can establish by written documentation: (i) is known to the recipient as evidenced by its written records before receipt thereof from the disclosing Party, (ii) is disclosed to the recipient free of confidentiality obligations by a Third Party who has the right to make such disclosure, (iii) is or becomes part of the public domain through no fault of the recipient, or (iv) the recipient can reasonably establish is independently developed by persons on behalf of recipient without access to or use of the information disclosed by the disclosing Party.

1.1.10 "Customer Demand" means, with respect to a Customer during a given period of time, the number of units of Product ordered by such Customer and shipped from EyePoint, its Affiliate, or an EyePoint distributor during such period of time.

1.1.11 "<u>Customers</u>" [\*\*\*]

1.1.12 "Dexycu" means the EyePoint product referred to by EyePoint as "Dexycu," which comprises nine percent (9%) dexamethasone intraocular suspension for ophthalmic use, together with all modifications, improvements, and enhancements thereto.

1.1.13 "EW Healthcare Entities" means EW Healthcare Partners, L.P., a Delaware limited partnership, and each of its Affiliates.

1.1.14 "<u>EyePoint Marks</u>" means those certain trademarks, trade names, designs and markings owned or licensed by EyePoint set forth on Exhibit A or designated from time to time in writing by EyePoint as available for use by Imprimis under this Agreement in connection with the promotion, marketing and solicitation of orders for the Products in the Territory.

1.1.15 "FDA" means the Food and Drug Administration of the United States or any successor thereto.

1.1.16 "GAAP" means United States generally accepted accounting principles.

1.1.17 "Group A Customers" [\*\*\*]

1.1.18 "Group B Customers" [\*\*\*].

1.1.19 "<u>HIPAA</u>" means the Health Insurance Portability and Accountability Act of 1996 and the rules and regulations promulgated under

its authority.

1.1.20 "Joint Steering Committee" means the committee comprising representatives of EyePoint and Imprimis described in Section 7.2.1.

1.1.21 "Legal Manufacturer" means the Person with legal authority to design, manufacture, package and label a product or device before it is placed on the market, regardless of whether these operations are carried out by that Person itself or on its behalf by another Person.

1.1.22 "<u>Marketing Materials</u>" means, with respect to a Product, all advertising, promotional, sales, social media and other related literature and materials for such Product provided or approved from time to time by EyePoint after consultation with Imprimis, each as modified in writing from time to time by EyePoint in its sole discretion after consultation with Imprimis. The applicable Marketing Materials for any Product may be determined by EyePoint after consultation with Imprimis with respect to specific Product, specific Customer or the specific circumstances of any specific sale.

1.1.23 "Minimum Sales Period" [\*\*\*]

1.1.24 "Minimum Year" means (a) [\*\*\*] of the Term and (b) beginning on [\*\*\*]thereafter during the Term.

1.1.25 "<u>Net Sales</u>" means the aggregate gross sales of Product invoiced to Third Party customers in the United States (or are Affiliates who are the end users of such Product) by EyePoint or its Affiliates, less: (a) returns, credits, allowances, discounts and rebates (including volume-based rebates) accrued with respect to such customers, (b) an allowance for bad debts, and (c) fees actually paid to distributors and specialty pharmacies for distribution of such Product, in each case of (a) through (c), as determined in accordance with GAAP.

1.1.26 "<u>Net Selling Price</u>" means the average price paid for a unit of Product by all customers in the United States during a given period of time based on EyePoint's and its Affiliates' net Product revenue reported in its financial statements for such period divided by the total number of units of Product sold by EyePoint and its Affiliates to its distributors during the corresponding period. Net product revenue will include deductions for (a) returns, credits, allowances, discounts and rebates (including volume-based rebates) to the account of such customers, (b) an allowance for bad debts, and (c) fees actually paid to distributors and specialty pharmacies for distribution of such Product, in each case of (a) through (c), as determined in accordance with GAAP. For avoidance of doubt, any Product shipped by EyePoint or its Affiliates or distributors as samples are specifically excluded from this calculation.

1.1.27 "<u>Pass-Through Payment Status</u>" means the designation of Dexycu by the United States Centers for Medicare & Medicaid Services, or any successor thereto, of "pass-through" payment status pursuant to Section 1833(t)(6) of the Social Security Act or its related regulations.

1.1.28 "<u>Person</u>" means an individual, corporation, partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.1.29 "Product" means Dexycu.

1.1.30 "<u>Registration</u>" means any registration, license, permit or governmental approval or clearance necessary for the purchase, distribution, promotion, marketing or sale of the Products in the Territory.

1.1.31 "Tax" or "Taxes" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon), other than corporate income taxes or comparable taxes assessed on net profits payable by Imprimis.

1.1.32 "Territory" means the United States of America, together with its territories and possessions.

1.1.33 "Third Party" means any Person other than EyePoint, Imprimis and their respective Affiliates.

1.1.34 "Tri-moxi" means the Imprimis product referred to by Imprimis as "Tri-moxi" and that includes as ingredients triamcinolone acetonide, moxifloxacin hydrochloride and poloxamer 407.

1.2 Interpretation. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include" and "contain" (and their variant forms) shall be deemed to be followed by the phrase "without limitation." The word "will" shall be construed to have the same meaning and effect as the word "shall." "US Dollar" or "\$" as used in this Agreement means the lawful currency of the United States. Any reference to any laws, codes or regulations herein shall be construed as referring to such laws as from time to time enacted, repealed or amended. The words "herein," "hereof" and "hereunder," and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof. The term "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase "and/or." Any reference herein to any Person shall be construed to include the Person's permitted successors and assigns. The headings used in this Agreement are for convenience only and shall not affect in any way the meaning or interpretation of this Agreement or any provision hereof.

## 2. Representations and Warranties.

2.1 <u>Mutual Representations and Warranties</u>. Each Party hereby represents and warrants to the other Party as follows:

2.1.1 Such Party is a duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.

2.1.2 Such Party (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary actions on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and, assuming the accuracy of the representations and warranties made by the other Party in this Section 2.1.2, constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

2.1.3 All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained.

2.1.4 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder do not conflict with or violate any requirement of applicable laws or regulations.

2.1.5 There is no litigation pending or, to such Party's knowledge, without having made an independent investigation, threatened against such Party or any of its Affiliates with respect to the transactions and activities contemplated by this Agreement.

2.2 Imprimis Representations and Warranties and Covenants. Imprimis hereby represents, warrants and covenants to EyePoint that: (a) as of the Effective Date, the customers set forth on Exhibit B constitute [\*\*\*]of Tri-moxi (by revenue); (b) it has the requisite personnel, facilities, equipment, expertise, experience and skill to perform its obligations hereunder; (c) it shall perform its obligations hereunder in accordance with all applicable laws (including all applicable FDA or other regulatory authority requirements), this Agreement and generally accepted professional standards; (d) it shall, and its representatives and agents shall, comply with applicable policies of EyePoint (which shall be delivered and/or communicated to applicable Imprimis employees, representatives and agents as promptly as practicable following the Effective Date) regarding the proper conduct of its representatives and agents in their interactions with customers; and (e) as of the Effective Date, it has unilaterally elected to wind down the manufacture, promotion and sale of Tri-moxi.

2.3 EyePoint Representations and Warranties and Covenants. EyePoint hereby represents, warrants and covenants to Imprimis that: (a) it shall perform its obligations hereunder in accordance with, all applicable laws (including cGMP and all applicable FDA or other regulatory authority requirements), this Agreement and generally accepted professional standards; and (b) as of the Effective Date, to the best of EyePoint's knowledge after due inquiry, neither Product nor any use thereof infringes, misappropriates or otherwise violates the intellectual property rights of any Third Party. Without limiting the generality of clause (a) above, EyePoint hereby represents, warrants and covenants to Imprimis that (i) EyePoint shall comply with the applicable requirements with respect to the "discount" exception as set forth in 42 U.S.C. § 1320a-7b(b)(3)(A) or the "discount safe harbor" as set forth in 42 C.F.R. § 1001.952(h) and shall account for any applicable discounts, rebates or price concessions to the extent required to comply with its price reporting obligations, and (ii) Eyepoint shall take any customer rebates into account in its calculation of the average sales price and Medicaid best price of Dexycu in accordance with applicable regulations.

2.4 <u>DISCLAIMERS</u>. WITH THE EXCEPTION OF THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN THIS SECTION 2, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES TO THE OTHER PARTY, EXPRESS OR IMPLIED. EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL OTHER REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL (INCLUDING ANY WARRANTY OF TITLE, MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT) TO THE EXTENT PERMITTED BY APPLICABLE LAW.

## 3. Appointment as Independent Agent.

3.1 <u>Appointment</u>. EyePoint hereby appoints Imprimis as a non-exclusive independent agent of EyePoint and its Affiliates to promote and market Product to, and to solicit orders for Product from, Customers solely in the Territory, on the terms and conditions set forth in this Agreement. Imprimis hereby accepts such appointment.

3.2 <u>Sub-Agents</u>. Imprimis shall have the right to appoint or authorize sub-agents under this Agreement only with EyePoint's prior written consent, which shall not be unreasonably withheld, conditioned or delayed. Imprimis shall be responsible for each such sub-agent's compliance with all terms and conditions of this Agreement applicable to Imprimis and shall be liable for any and all breaches by such sub-agent thereof.

## 3.3 Products.

3.3.1 The rights granted to Imprimis hereunder relate solely to the Products on the terms and conditions of this Agreement. Imprimis shall have no right to promote, market or solicit orders for any other EyePoint product unless otherwise expressly approved in writing by EyePoint in its sole discretion. Imprimis is not granted any right or license to sell or distribute Product.

3.3.2 Neither Imprimis nor any of its Affiliates shall act as an agent or as a legal representative of EyePoint or its Affiliates, and Imprimis and its Affiliates shall not have any right or power to act for or bind EyePoint or its Affiliates in any respect or to pledge its credit. The detailed operations of each Party and its Affiliates under this Agreement are subject to the sole control and management of such Party and its Affiliates.

3.4 <u>Customer Inquiries</u>. From and after [\*\*\*]days after the Effective Date, if Imprimis receives a bona fide inquiry for sale of Product from a Third Party that is not an existing Customer, Imprimis shall have the right to provide written notice thereof to EyePoint, which notice shall identify the applicable Third Party. Such Third Party may be added as a Customer by the Commercialization Committee, which shall also determine Baseline Period and Baseline Quarterly Amount for such Customer, if any. Notwithstanding anything to the contrary herein, if (a) any such Third Party has not purchased at least [\*\*\*]units of Product in the [\*\*\*]month period prior to Imprimis' written notice set forth above, (b) such Third Party is not added as a Customer by the Commercialization Committee, and (c) such Third Party purchases Product within [\*\*\*]months after Imprimis' written notice, then such Third Party shall automatically be added as a Customer hereunder effective as of the date of such written notice. For the avoidance of doubt, any Product inquiries received by Imprimis from potential Customers prior to the end of such [\*\*\*]day period, and not previously included under the definition of "Customers" herein, may be disclosed to EyePoint by written notice and addressed on a case-by-case basis by the Commercialization Committee. Notwithstanding the preceding sentence, in the event a prospective Customer has commenced Product training; Imprimis shall then promptly disclose to EyePoint a written summary of communications Imprimis is having or has had with such prospective Customer; and then the status of such prospective Customer shall be addressed on a case-by-case basis by mutual agreement of the Parties.

3.5 <u>No Rights or Licenses</u>. Only rights and licenses expressly granted herein shall be of legal force and effect. No license or other right shall be created hereunder by implication, estoppel or otherwise.

3.6 <u>Pricing</u>. Notwithstanding any other provision of this Agreement, EyePoint shall have sole decision-making authority with respect to the price of any Product. Further, for purposes of clarity and the avoidance of doubt, without the express written consent of EyePoint, which EyePoint may withhold, condition or refuse in its sole and absolute discretion, at no time shall Imprimis or its Affiliates, representatives or agents, promote, create or establish bundled offerings or package deals for the Product in combination with any other product or service.

3.7 Limited Exclusivity. EyePoint shall not knowingly or intentionally perform any act that could reasonably conflict with EyePoint's appointment of Imprimis as an independent agent. In addition to and without limiting the generality of the foregoing, EyePoint (a) shall not (and shall cause its Affiliates not to) engage or appoint any Third-Party compounding pharmacy or outsourcing facility (as defined and described in 21 U.S.C. §353a and §353b) as an independent sales agent for Product in the Territory, and (b) shall not solicit, initiate or encourage submission of proposals or offers from any Third-Party compounding pharmacy or outsourcing facility in the Territory. For the avoidance of doubt, this excludes any contractual relationship EyePoint may have or may enter into with its customers or distributors, or with third parties related to such relationships, such as group purchasing organizations, from time-to-time.

3.8 Non-Circumvention. EyePoint shall not, knowingly or intentionally, do any of the following:

3.8.1 enter into any transaction with any sub-agent of Imprimis or of Imprimis', its Affiliate's, or its sub-agent's employees, contractors or consultants similar to, in competition with, or which could have the effect of preventing Imprimis from receiving the full benefit of the appointment under Section 3.1;

3.8.2 solicit any of the foregoing to enter into any such a transaction; or

3.8.3 induce, solicit, procure or otherwise encourage any of EyePoint's Affiliates or distributors to enter into any such transaction.

## 4. Covenants of Imprimis.

## 4.1 Marketing, Promotion and Solicitation of Orders.

4.1.1 Imprimis shall use Commercially Reasonable Efforts to cause Customers to become customers for Product and to promote and market the Product in the Territory and subject to and otherwise in accordance with the terms and conditions of this Agreement. Imprimis shall dedicate no fewer of its sales representatives, sub-agents and approved contractors on a full time basis with Product as their highest priority and primary promoted product throughout the duration of the Term than may be reasonably necessary to cause the Customers to become customers for Product. Imprimis shall ensure that all such sales representatives, sub-agents and approved contractors are trained by Imprimis to be familiar with all appropriate requirements of this Agreement which are relevant to their performance of their duties as a sales agent for the Product.

4.1.2 Imprimis shall not use any advertising, promotional or other sales literature or materials to promote or market the Products other than the Marketing Materials or other literature or materials expressly approved in advance in writing by EyePoint. Notwithstanding the foregoing, if EyePoint provides Imprimis with electronic copies of any Marketing Materials, Imprimis shall have the right to make copies thereof to the extent necessary to perform its obligations under this Agreement. Imprimis shall not make any false or misleading statement, or any representation or warranty, oral or written, to any Third Party concerning the Products that is inconsistent with, in excess of, or contrary to, the Marketing Materials or other literature or materials expressly approved in advance in writing by EyePoint, or that is disparaging to the Products, EyePoint or any of EyePoint's Affiliates.

4.1.3 Imprimis shall adhere to EyePoint's ordering and distribution system with respect to all orders for the Products from Customers in the Territory that it receives.

4.1.4 If any Third Party makes an inquiry regarding a Product or its use, Imprimis shall promptly address such matter in accordance with procedures and other instructions provided in writing by EyePoint; provided, however, that (a) if such inquiry specifically relates to customer service or product support for a Product, Imprimis shall forward such inquiry to EyePoint; and (b) if such inquiry relates to a warranty claim or other complaint related to a Product, then Imprimis shall provide to EyePoint all information reasonably related thereto.

4.2 <u>Reports</u>. At each meeting of the Commercialization Committee, Imprimis shall report to EyePoint in writing as well as orally summarizing in reasonable detail its and its approved sub-agents' sales calls or other contacts with, and the progress and development of Customers for the Products in the Territory.

4.3 Warranty Claims. Imprimis shall promptly notify EyePoint of each customer warranty claim relating to a Product received by Imprimis.

4.4 <u>Recalls</u>. In the event of a Product incident, recall or field safety corrective action initiated by or on behalf of EyePoint or by a regulatory agency or court, following written notice thereof from EyePoint, Imprimis shall reasonably cooperate with EyePoint in effecting the reporting of an incident or the recall of the affected Products. EyePoint shall be responsible, at its sole expense, for conducting any recalls or field safety corrective actions pertaining to the Products, and EyePoint shall reimburse Imprimis for all out-of-pocket costs and expenses reasonably incurred by Imprimis in cooperating with EyePoint pursuant to the terms of this Section 4.4, except to the extent such costs and expenses result from Imprimis' gross negligence, fraud or willful misconduct.

4.5 <u>Cooperation with EyePoint</u>. Imprimis shall provide such assistance as reasonably requested by EyePoint in connection with all Registrations for the Products, and all contacts with the applicable regulatory authorities in connection therewith, reasonably required to permit Imprimis to promote and market the Products to, and to solicit orders for the Products, from Customers in the Territory pursuant to the terms of this Agreement.

## 5. Covenants of EyePoint.

5.1 <u>Training for Imprimis Personnel</u>. EyePoint shall provide Imprimis technical and sales personnel with such training regarding the Products as EyePoint customarily provides to its personnel. Such training shall be conducted at such reasonable times and places as mutually agreed by the Parties.

5.2 <u>Marketing, Promotion and Sales Support</u>. EyePoint, in collaboration with Imprimis, shall support the marketing, promotion and sales of the Products by Imprimis in the Territory by the following:

5.2.1 EyePoint shall use Commercially Reasonable Efforts to maintain all necessary Registrations and patent rights or other intellectual property rights related to Product.

5.2.2 EyePoint or its Affiliates shall provide Imprimis with (a) reasonable access to and assistance of its technical, sales, and service personnel, (b) reasonable technical information regarding Products, and (c) reasonable product specialist detailing and sales support, in each case, as reasonably necessary to support Imprimis detail calls regarding Products with Imprimis existing or future Customers in the Territory, as EyePoint customarily provides in the Territory, and without charge to Imprimis except as may be otherwise mutually agreed in writing.

5.2.3 EyePoint shall provide Imprimis with electronic or hard copies of Marketing Materials, package inserts and labeling, and technical information regarding the Products and their proper use.

5.3 Orders and Distributor Portal Access. If Imprimis receives an order for Product (from a Customer or other Third Party), it shall promptly transmit such order to EyePoint through EyePoint's authorized distributors for the Product for acceptance or rejection. EyePoint's distributors shall have final authority to accept or reject customer orders, subject to normal evaluation of creditworthiness, contract coverage or other reasonable customer acceptance measures as such EyePoint distributors of EyePoint, nor shall Imprimis represent explicitly or implicitly to any Third Party that it has such authority. With respect to Customers, EyePoint shall provide Imprimis with access to its distributors' electronic ordering, inventory, and sales portals for the Product, and to the extent such access is unavailable, EyePoint shall notify Imprimis in writing of such acceptance of Customer orders within fifteen (15) days after receipt thereof.

5.4 <u>Inventory</u>. Promptly after Imprimis' reasonable request from time to time, EyePoint shall disclose to Imprimis the current inventory of Product held by EyePoint's distributors. EyePoint shall use Commercially Reasonable Efforts to ensure that its distributors maintain inventory of Product sufficient to meet anticipated customer demand for Product. Imprimis shall provide to EyePoint, on a quarterly basis, a rolling twelve-month forecast of projected sales of Product to Customers.

5.5 Quarterly Reports. Promptly after the end of each calendar quarter during the term of the Agreement, EyePoint shall provide Imprimis with a report setting forth in such detail as reasonably requested by Imprimis the volume of Product sales for such quarter for each Customer of Product.

5.6 <u>Sale and Shipment</u>. With respect to each order for Product by a Customer accepted by an EyePoint distributor, EyePoint shall use Commercially Reasonable Efforts to ensure that such distributor (or any other distributor) sells and ships (or cause to sell and ship) such Product to such Customer in accordance with such order.

5.7 Warranty Claims and Returns. As between the Parties, EyePoint shall be responsible for all warranty claims and returns for Products.

5.8 <u>Registrations</u>. EyePoint shall be solely responsible for obtaining and maintaining any Registrations, in the name of EyePoint, that may be necessary to permit the promotion, marketing and sale of the Products in the Territory. EyePoint shall own and maintain all regulatory filings and Registrations for the Products in its own name, shall be the Legal Manufacturer of the Products, and shall be responsible for and act as the sole point of contact with the applicable regulatory authorities in connection therewith.

5.9 Pass-Through Status. EyePoint shall use Commercially Reasonable Efforts to maintain Pass-Through Payment Status, and, if Pass-Through Payment Status ceases, EyePoint shall promptly notify Imprimis in writing thereof.

6. [\*\*\*].

7. Governance.

#### 7.1 Commercialization Committee.

7.1.1 The Commercialization Committee shall comprise one (1) representative of EyePoint and one (1) representative of Imprimis, each with appropriate decision making authority on behalf of such Party. Each Party shall appoint its representative to the Commercialization Committee prior to the first meeting thereof, and may substitute its representative from time to time, in its sole discretion, effective upon written notice to the other Party of such change, but shall use commercially reasonable efforts to maintain stability of Commercialization Committee representation.

7.1.2 The purpose of the Commercialization Committee under this Agreement shall be (a) to facilitate the exchange of information between the Parties, (b) to review and discuss the activities of the Parties under this Agreement, (c) to review, consider and make recommendations for modifications to the Marketing Materials, (d) to add Third Parties referred under Section 3.4 as Customers to this Agreement and to determine the Baseline Period for such Customers pursuant to criteria mutually agreed by the Parties in writing, and (e) to review other information relating to Products.

7.1.3 The Commercialization Committee shall meet at such places or in such forms (such as by telephone conference) as determined by mutual agreement of the Parties. Each Party may permit such visitors to a meeting of the Commercialization Committee as mutually agreed by the Parties prior to such meeting; provided, that a Party may require each such visitor to execute an appropriate confidentiality agreement. Each Party shall be responsible for its own costs in connection with the meetings of the Commercialization Committee. The representative of each Party shall be entitled to one (1) vote. Except as expressly provided herein, each determination or other action of the Commercialization Committee shall require unanimous approval by the representatives of both Parties. If the Commercialization Committee is unable to reach such unanimous approval, then each Party shall have the right to escalate the applicable issue to the Joint Steering Committee upon written notice to the other Party.

7.1.4 The first meeting of the Commercialization Committee shall occur within two (2) business days after the Effective Date. Thereafter, for the first thirty (30)-day period following the Effective Date, the Commercialization Committee shall meet weekly. After such thirty (30)-day period, the Commercialization Committee shall meet no less frequently than monthly.

7.1.5 Within ten (10) days after each Commercialization Committee meeting, a Commercialization Committee representative of one of Parties, on an alternating basis, shall prepare and provide to each Party a copy of the minutes of such meeting which shall set forth, in reasonably specific detail, the discussions and any approval, determination or other action agreed to by all of the members of the Commercialization Committee. Such minutes shall be subject to the reasonable comment and approval by the other Party.

## 7.2 Joint Steering Committee.

7.2.1 The Joint Steering Committee shall comprise an equal number of representatives of EyePoint and of Imprimis, as determined by mutual agreement of the Parties. Initially, the Joint Steering Committee shall comprise one (1) C-suite executive of EyePoint as EyePoint's representative and one (1) board member or C-suite executive of Imprimis as Imprimis' representative. Each Party shall appoint its representative to the Joint Steering Committee prior to the first meeting thereof, and from time to time may substitute its representative with another C-suite executive decision maker of such Party, in its sole discretion, effective upon written notice to the other Party of such change, but shall use commercially reasonable efforts to maintain stability of Joint Steering Committee representation.

7.2.2 The purpose of the Joint Steering Committee under this Agreement shall be (a) to resolve disputes of the Commercialization Committee, (b) to oversee the Commercialization Committee and otherwise review and discuss the activities of the Parties under this Agreement and (c) from time to time, to establish subcommittees to oversee particular projects or activities under this Agreement. Any subcommittee shall be constituted and shall operate as determined by the Joint Steering Committee.

7.2.3 The Joint Steering Committee shall meet at such places or in such forms (such as by telephone conference) as determined by mutual agreement of the Parties. Each Party may permit such visitors to a meeting of the Joint Steering Committee as mutually agreed by the Parties prior to such meeting. Each Party shall be responsible for its own costs in connection with the meetings of the Joint Steering Committee. The representative of each Party shall be entitled to one (1) vote. Except as expressly provided herein, each determination or other action of the Joint Steering Committee shall require unanimous approval by the representatives of both Parties. [\*\*\*].

7.2.4 The Joint Steering Committee shall meet no less frequently than quarterly.

7.2.5 Within ten (10) days after each Joint Steering Committee meeting, a Joint Steering Committee representative of one of Parties, on an alternating basis, shall prepare and provide to each Party a copy of the minutes of such meeting which shall set forth, in reasonably specific detail, the discussions and any approval, determination or other action agreed to by all of the members of the Joint Steering Committee. Such minutes shall be subject to the reasonable comment and approval by the other Party.

## 8. Financial Terms and Conditions.

8.1 <u>Remittance Amount</u>. EyePoint shall calculate a remittance amount, representing a sales commission to Imprimis, for each calendar quarter based on the following formula: [\*\*\*]. This calculation will be prepared separately for Group A Customers, Group B Customers and any future Customers added by the Commercialization Committee. For clarity, for a Customer added to this Agreement during a calendar quarter, "A" will include only that portion of Customer Demand for that portion of such quarter that such Customer constitutes a Customer hereunder, and "B" will include only the corresponding Baseline Demand for such portion of such quarter for such Customer.

8.2 <u>Reports</u>. Within twenty-one (21) days after the end of each calendar quarter during the term of this Agreement, EyePoint shall deliver to Imprimis a report estimating in reasonable detail for such calendar quarter a calculation of the applicable Remittance Amount, including the Customer Demand and Baseline Quarterly Amount for each Customer.

#### 8.3 Payment Terms.

8.3.1 The Remittance Amount shown to have accrued by each report provided for under Section 8.2 shall be due within [\*\*\*]after the end of the applicable calendar quarter other than the last calendar quarter in each applicable calendar year. A prepayment of a portion of the Remittance Amount shall be made in accordance with Section 8.3.2.

8.3.2 Within thirty (30) days after the end of each applicable calendar quarter, EyePoint shall pay to Imprimis a prepayment of a portion of the Remittance Amount for such calendar quarter equal to the Remittance Amount for the immediately preceding calendar quarter divided by three (3). Notwithstanding the preceding sentence, there shall be no prepayment of the Remittance Amount for a particular quarter if the Remittance Amount for such calendar quarter is lower than the calculated prepayment. The Parties shall discuss in good faith on an annual basis any potential adjustments to the foregoing prepayment amount based on EyePoint's then calculated receivables days outstanding.

8.3.3 EyePoint shall have the right to reasonably estimate the Customer Demand and Net Selling Price for purposes of its payment and reporting obligations under Section 8.2 and this Section 8.3 determined in good faith based on the most current data then available to EyePoint; provided, however, that EyePoint shall substitute the actual value for such Customer Demand, recalculate the Remittance Amount, and update its report under Section 8.2 prior to or by the following annual reconciliation set forth in Section 8.4.

8.4 <u>Annual Reconciliation</u>. Within one hundred twenty (120) days after the end of each calendar year, EyePoint will conduct a final calculation of the full calendar year Remittance Amount. Such calculation will be based on the Net Selling Price and the Customer Demand (each, as calculated for the full calendar year). If the Remittance Amount actually paid is less than the amount calculated pursuant to such annual review process, then EyePoint shall promptly pay to Imprimis an amount equal to such underpayment. If the Remittance Amount actually paid is greater than the amount calculated pursuant to such annual review process, then EyePoint may reduce the amount of the Remittance Amount payable pursuant to Section 8.3.1 or direct Imprimis to (and Imprimis shall promptly) pay to EyePoint an amount equal to such overpayment.

8.5 <u>Records Retention</u>. For a period of two (2) years after payment of the applicable Remittance Amount, EyePoint shall, and shall cause its Affiliates to, keep and maintain complete and accurate books and records pertaining to calculation of Customer Demand, Net Selling Price, Net Sales and the Remittance Amount, and in sufficient detail to confirm the accuracy of the calculations of Customer Demand, Net Selling Price and the Remittance Amount payments hereunder.

8.6 <u>Audits</u>. Upon the written request of Imprimis and not more than once in each calendar year, EyePoint shall permit an independent certified public accounting firm selected by Imprimis and reasonably acceptable to EyePoint, at Imprimis' expense, to have access during normal business hours to such of the financial records of EyePoint associated with this Agreement as may be reasonably necessary to verify the accuracy of the Remittance Amount reports hereunder for the eight (8) calendar quarters immediately prior to the date of such request. If such accounting firm concludes that additional amounts were owed during the audited period, EyePoint shall pay such additional amounts within thirty (30) days after the date Imprimis delivers to EyePoint such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by Imprimis; provided, however, if the audit discloses that the Remittance Amount payable by EyePoint for such period are more than one hundred five percent (105%) of the Remittance Amount actually paid for such period, then EyePoint shall pay the reasonable fees and expenses charged by such accounting firm. Imprimis shall cause its accounting firm to retain all financial information subject to review under this Section 8.6 in strict confidence. Imprimis shall treat all such financial and other disclosed information as EyePoint's confidential information and shall not disclose such financial information to any Third Party or use it for any purpose other than as specified in this Section 8.6.

9. <u>Limited Warranty</u>. THE LIMITED WARRANTY FOR A PRODUCT SHALL BE ONLY AS SET FORTH ON THE INSERT ACCOMPANYING THE APPLICABLE PRODUCT. For the avoidance of doubt, Imprimis never takes legal title to any Product under this Agreement, and any Product warranty matters as between EyePoint and its customers are under the control and responsibility of EyePoint.

## 10. Confidentiality.

10.1 <u>Confidential Information</u>. During the term of this Agreement, and for a period of ten (10) years following the expiration or earlier termination hereof, each Party shall maintain in confidence all Confidential Information of the other Party or its Affiliates (including all Confidential Information disclosed prior to the term of this Agreement pursuant to a written confidentiality agreement between the Parties), and shall not use, disclose or grant the use of the Confidential Information of the other Party except on a need-to-know basis to those directors, officers, employees, consultants or permitted assignees, to the extent such use or disclosure is reasonably necessary in connection with such Party's activities as expressly authorized by this Agreement. To the extent that disclosure is authorized by this Agreement, prior to disclosure, each Party hereto shall obtain agreement of any such Person to hold in confidence and not make use of the Confidential Information of the other Party for any purpose other than those permitted by this Agreement. Each Party shall notify the other promptly upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

10.2 Terms of this Agreement. Except as otherwise provided in this Section 10, during the term of this Agreement and for a period of ten (10) years thereafter, neither Party shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party; provided, however, that a Party may disclose the terms and conditions of this Agreement, (a) in confidence on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, (b) in confidence in connection with the enforcement of this Agreement or rights under this Agreement, and (c) to a Third Party in confidence in connection with an actual or proposed (i) equity investment in, or a strategic alliance with, such Party or (ii) Change of Control of such Party. Notwithstanding the foregoing, prior to execution of this Agreement, the Parties have agreed in writing upon the substance of information that can be used to describe the terms of this transaction, and each Party may disclose such information, as modified by mutual agreement from time to time, without the other Party's consent.

10.3 <u>Permitted Disclosures</u>. The confidentiality obligations contained in this Section 10 shall not apply to the extent that a Party is required (a) in the reasonable opinion of such Party's legal counsel, to disclose information by applicable law, regulation, rule (including rule of a stock exchange or automated quotation system), order of a governmental agency or a court of competent jurisdiction or legal process, including tax authorities, or (b) to disclose information to any governmental agency for purposes of obtaining approval to test or market a product; provided, in either case ((a) or (b)), that, to the extent practicable, such Party shall provide written notice thereof to the other party and sufficient opportunity to object to any such disclosure or to request confidential treatment thereof. Notwithstanding anything to the contrary herein, each Party may disclose the terms and conditions of this Agreement to any Person with whom such Party has, or is proposing to enter into, a business relationship related to Product, as long as such Person has entered into a confidentiality agreement with such Party.

#### 11. Intellectual Property Rights.

11.1 <u>Patent Rights</u>. EyePoint does not, either expressly or impliedly, grant any licenses to Imprimis under any patents owned or otherwise controlled by EyePoint or under which EyePoint has any rights, except the right to promote, market and solicit orders for the Products on the terms and subject to the conditions of this Agreement.

11.2 EyePoint Marks. Subject to the terms and conditions of this Agreement and any reasonable use policy that may be provided in writing by EyePoint to Imprimis from time to time, EyePoint hereby grants to Imprimis a non-exclusive license (with the limited right to grant sublicenses to authorized sub-agents) to use the EyePoint Marks solely in connection with the promotion, marketing and soliciting orders for the Products in the Territory on the terms and subject to the conditions of this Agreement. Any goodwill associated with the EyePoint Marks affixed or applied or used in connection with the Products shall accrue to the sole benefit of EyePoint.

## 11.3 Copyrights.

11.3.1 Imprimis hereby acknowledges that EyePoint or a Third Party has claimed, or may claim, copyright protection with respect to certain parts of the Products and the labels, inserts, studies, publications, Marketing Materials, promotional materials, and other materials related to the Products. Imprimis shall not knowingly take any action which is in any way inconsistent with EyePoint's or such Third Party's claim of copyright protection with respect to such items.

11.3.2 For clarity, nothing contained in this Section 11.3 shall prohibit Imprimis from copying and distributing to its sales representatives or in connection with its commercialization of Products hereunder Marketing Materials or materials prepared by or on behalf of EyePoint for the purpose of fulfilling Imprimis' obligations under this Agreement, in each case, to the extent permitted hereunder. EyePoint hereby grants Imprimis a non-exclusive, royalty-free license (with the right to grant sublicenses to permitted sub-agents) to use, copy, display and distribute such materials solely for the purpose of fulfilling Imprimis' obligations under this Agreement.

#### 12. Indemnity.

12.1 By EyePoint. EyePoint shall defend, indemnify and hold harmless Imprimis, its sub-agents, its and their respective Affiliates, and its and their respective directors, officers, employees and agents from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) ("<u>Liabilities</u>") resulting from any claims, demands, actions or other proceedings by any Third Party ("<u>Third-Party Claim</u>") to the extent resulting from (a) the breach of any representation, warranty or covenant of EyePoint under this Agreement; (b) the use by any purchaser of, or any defect in, the Products, (c) the infringement, misappropriation or other violation of any intellectual property rights of a Third Party by or in connection with the Products; (d) the negligence or willful misconduct of EyePoint or any of its Affiliates in the performance of its obligations under this Agreement; (e) any fraud or misrepresentations by EyePoint; (f) the authorized use of the EyePoint Marks under this Agreement; or (g) any violation by EyePoint (or any of its directors, officers, employees, distributors or agents) of any applicable laws, regulations or court orders; provided, however, that the foregoing indemnity obligation shall not apply to the extent that any Liability arises from, is based on, or results from any matter set forth in Section 12.2 for which Imprimis has an indemnification obligation.

12.2 By Imprimis. Imprimis shall defend, indemnify and hold harmless EyePoint, its Affiliates, and their respective directors, officers, employees and agents, from and against all Liabilities resulting from any Third-Party Claim to the extent resulting from (a) the breach of any representation, warranty or covenant of Imprimis under this Agreement; (b) the negligence or willful misconduct of Imprimis or any of its Affiliates, including its sales representatives, in the performance of its obligations under this Agreement; (c) any fraud or misrepresentations by Imprimis, or (d) any violation by Imprimis (or any of its directors, officers, employees or agents) of any applicable laws, regulations or court orders, provided, however, that the foregoing indemnity obligation shall not apply to the extent that any Liability arises from, is based on, or results from any matter set forth in Section 12.1 for which EyePoint has an indemnification obligation.

12.3 Procedure. A Party seeking indemnification (the "Indemnitee") shall promptly notify the other Party (the "Indemnifying Party") in writing of a Third-Party Claim; provided, that an Indemnitee's failure to give such notice or delay in giving such notice shall not affect such Indemnitee's right to indemnification under this Section 12 except to the extent that the Indemnifying Party has been prejudiced by such failure or delay. The Indemnifying Party shall have the right to control the defense of all indemnification claims hereunder. The Indemnitee shall have the right to participate at its own expense in the Third-Party Claim with counsel of its own choosing. The Indemnifying Party shall consult with the Indemnitee in good faith with respect to all non-privileged aspects of the defense strategy. The Indemnitee shall cooperate with the Indemnifying Party as reasonably requested at the Indemnifying Party's sole cost and expense. The Indemnifying Party shall not settle or otherwise consent to an adverse judgment in any such Third-Party Claim that diminishes the rights or interests of the Indemnitee without the prior express written consent of the Indemnitee, which consent shall not be unreasonably withheld, conditioned or delayed.

#### 13. Term and Termination.

13.1 Term. Unless terminated earlier, or extended, pursuant to this Agreement or by mutual written agreement of the Parties, this Agreement shall commence on the Effective Date and shall expire on fifth (5th) anniversary thereof (the "Term").

13.2 <u>Termination for Convenience</u>. From and after August 1, 2021, provided that Imprimis has used Commercially Reasonable Efforts to market and promote Product to all Customers, Imprimis may terminate this Agreement for any reason or no reason upon twelve (12) months' prior written notice of termination to EyePoint. For the avoidance of doubt, the earliest date of termination possible pursuant to this Section 13.2 is July 31, 2022. Should Imprimis exercise this provision, no sales commissions, calculated as a Remittance Amount, will be payable for sales beyond the date of termination.

13.3 End of Pass-Through Payment Status. If Pass-Through Payment Status ceases, then either Party may terminate this Agreement by providing ninety (90) days' prior written notice of termination to the other Party promptly after the end of the calendar quarter in which Pass-Through Payment Status ceases.

## 13.4 Termination for Cause.

13.4.1 A Party may terminate this Agreement upon or after any material breach of this Agreement by the other Party if the other Party has not cured such breach within sixty (60) days after written notice thereof from the non-breaching Party.

13.4.2 If Imprimis fails to achieve bona fide Customer orders for quantities of Product to achieve the minimum sales level within the applicable minimum period (each as set forth in the table below), then EyePoint shall have the right to terminate this Agreement by providing sixty (60) days' prior written notice of termination to Imprimis within sixty (60) days after the end of such period:

Minimum Period	Minimum Sales Level (Customer Demand in excess of Baseline Demand for such period)
First Minimum Year	[***]
First Minimum Sales Period	[***]
Each subsequent Minimum Sales Period during the Term	[***]

13.5 <u>Change of Control</u>. If EyePoint undergoes a Change of Control, other than a Change of Control that results in an EW Healthcare Entity directly or indirectly controlling EyePoint, then EyePoint may terminate this Agreement by providing ninety (90) days' prior written notice of termination to Imprimis within thirty (30) days after such Change of Control.

## 13.6 Effect of Expiration or Termination.

13.6.1 Expiration or termination of this Agreement shall be without prejudice to any rights which shall have accrued to the benefit of a Party prior to such expiration or termination. In addition and without limiting the foregoing, Sections 2.4, 4.3, 4.4, 5.7, 9, 10, 12, 13.6 and 14 will survive any expiration or termination of this Agreement, and, unless a later survival end date is specified elsewhere in this Section 13.6, Sections 8.5 and 8.6 shall survive for a period of five (5) years after expiration or termination.

13.6.2 If Imprimis terminates this Agreement pursuant to Section 13.4.1, then Section 8 (other than Sections 8.5 and 8.6) shall additionally survive until the fifth (5th) anniversary of the Effective Date, and Sections 8.5 and 8.6 shall survive until the seventh (7th) anniversary of the Effective Date.

13.6.3 If EyePoint terminates this Agreement pursuant to Section 13.4.2, then Section 8 (other than Sections 8.5 and 8.6) shall not survive after termination and all payments under Section 8 expire on the date of termination, and Sections 8.5 and 8.6 shall survive for a period of three (3) years after termination.

13.6.4 If Imprimis terminates this Agreement pursuant to Section 13.2 all payments under Section 8 expire on the date of termination. Further section 13.5 will not apply if Imprimis terminates pursuant to Section 13.2.

13.6.5 If EyePoint terminates this Agreement pursuant to Section 13.5, then Section 8 (other than Sections 8.5 and 8.6) shall additionally survive until the fifth (5th) anniversary of the Effective Date, and Sections 8.5 and 8.6 shall survive until the seventh (7th) anniversary of the Effective Date, except that the Remittance Percentages set forth in Section 8.1 shall equal the applicable percentage(s) for the applicable period(s) as set forth in the table below instead of [\*\*\*]:

Calendar Year of Termination	Remittance Percentage
2021, 2022, or 2023	[***] for the twelve (12)-month period commencing on termination
	[***] for the following twelve (12)-month period
	[***]thereafter until the fifth (5th) anniversary of the Effective Date
2024	[***] for the twelve (12)-month period commencing on termination
	[***]thereafter until the fifth (5th) anniversary of the Effective Date
2025	[***]until the fifth (5th) anniversary of the Effective Date

13.6.6 Except as otherwise expressly set forth in this Agreement, promptly upon the expiration or earlier termination of this Agreement, each Party shall return to the other Party all tangible items regarding the Confidential Information of the other Party and all copies thereof, provided, <u>however</u>, that each Party shall have the right to retain one (1) copy for its legal files for the sole purpose of determining its obligations hereunder and for purposes of exercising any rights that survive expiration or termination hereunder.

## 14. Miscellaneous.

14.1 <u>HIPAA Requirements</u>. Without limiting the generality of anything set forth in this Agreement, each Party shall comply with all applicable regulations promulgated under HIPAA, including the federal privacy regulations contained in 45 C.F.R. Parts 160 and 164, the federal security standards contained in 45 C.F.R. Part 142, and the federal standards for electronic transactions contained in 45 C.F.R. Parts 160 and 162 (the "<u>HIPAA Requirements</u>"). Each Party shall not use or further disclose any protected health information as described in the HIPAA Requirements, other than as permitted by HIPAA Requirements and the terms of this Agreement. Each Party shall make its internal practices, books, and records relating to the use and disclosure of Protected Health Information (as defined in HIPAA) available to the Secretary of Health and Human Services to the extent required for determining compliance with the HIPAA Requirements.

14.2 <u>Conduct of Business</u>. Each of Imprimis and EyePoint shall use Commercially Reasonable Efforts to conduct its business in a manner that reflects favorably on the reputation of each of EyePoint and Imprimis, respectively; provided, that this shall not limit a Party's ability to fully exercise its rights under this Agreement.

14.3 <u>Compliance with Laws</u>. Each of EyePoint and Imprimis shall comply with any and all governmental laws, regulations and orders applicable to the Registration, promotion, marketing, sale and distribution of the Products in the Territory and to relationships with health care professionals, including, with respect to Imprimis, any requirement to be registered as EyePoint's independent agent with any governmental authority.

14.4 <u>Insurance</u>. Each Party shall maintain self-insurance or general commercial liability insurance, including contractual liability insurance and product liability insurance against claims regarding its activities contemplated by this Agreement, in each case in such amounts as it customarily maintains for similar products and activities. Each Party shall maintain such insurance during the term of this Agreement and thereafter for so long as it maintains insurance for itself covering such activities.

14.5 <u>Expenses</u>. Each of Imprimis and EyePoint shall be responsible for all of its own expenses and employees in connection with its activities contemplated by this Agreement. Neither Imprimis nor EyePoint shall incur any expense chargeable to such other Party, except as may be specifically authorized in advance in writing in each case by such other Party.

14.6 <u>Entire Agreement</u>. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. The Exhibits attached hereto constitute part of this Agreement. All express or implied representations, agreements and understandings with respect to the subject matter hereof, either oral or written, heretofore made are expressly superseded by this Agreement.

14.7 <u>Amendments</u>. No amendment or modification of the terms of this Agreement shall be binding on either Party unless reduced to writing and signed by an authorized officer of the Party to be bound.

14.8 <u>Waiver</u>. No waiver by one Party of the other Party's obligations, or of any breach or default hereunder by any other Party, shall be valid or effective, unless such waiver is set forth in writing and is signed by the Party giving such waiver; and no such waiver shall be deemed a waiver of any subsequent breach or default of the same or similar nature or any other breach or default by such other Party.

14.9 <u>Further Assurances</u>. EyePoint and Imprimis each shall perform any and all further acts and execute and deliver any and all further documents and instruments that may be necessary to carry out the provisions of this Agreement.

14.10 <u>Notices</u>. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective upon receipt by the addressee.

If to EyePoint:	EyePoint Pharmaceuticals, Inc. 480 Pleasant Street, Suite B300 Watertown, Massachusetts 02472 Attention: Chief Executive Officer
If to Imprimis:	ImprimisRx, LLC 12264 El Camino Real, Suite 350 San Diego, California 92130 Attention: President

14.11 <u>Assignment</u>. Except as otherwise expressly provided under this Agreement, neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred (whether voluntarily, by operation of law or otherwise), without the prior express written consent of the other Party, <u>provided</u>, <u>however</u> that either Party may, without such consent, assign this Agreement and its rights and obligations hereunder in whole or in part (i) to an Affiliate of such Party, or (ii) in connection with the Change of Control of such Party or to a Third Party successor of such Party to all or substantially all of the business to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment or transfer in violation of this Section 14.11 shall be void.

14.12 <u>Governing Law</u>. This Agreement shall be construed and enforced in accordance with the laws of the State of Delaware, without regard to the conflicts of law principles thereof, and shall not be governed by the United Nations Convention on Contracts for the International Sale of Goods.

14.13 <u>Dispute Resolution</u>. Any and all disputes or claims arising from or out of this Agreement shall be litigated exclusively before a court of the State of Delaware or, if subject matter jurisdiction exists, the United States District Court for the District of Delaware. Each Party hereby irrevocably and unconditionally consents to the exclusive personal jurisdiction and service of, and venue of, any such court, and further irrevocably and unconditionally waives and agrees not to plead or claim that any action, lawsuit or proceeding brought in any such court has been brought in an inconvenient forum. Any judgment issued by such a court may be enforced in any court having jurisdiction.

14.14 <u>LIMITATION OF LIABILITY</u>. WITHOUT LIMITING THE RIGHTS OR REMEDIES OF THE PARTIES REGARDING (A) THE OBLIGATIONS TO INDEMNIFY, DEFEND AND HOLD HARMLESS PURSUANT TO SECTION 12, (B) A BREACH OF THE CONFIDENTIALITY OBLIGATIONS PURSUANT TO SECTION 10, OR (C) A CLAIM ARISING OUT OF FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER FORESEEABLE OR NOT, ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

14.15 <u>Severability</u>. If any provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, then (a) such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or invalidate or render unenforceable such provision in any other jurisdiction, and (b) such provision, in such jurisdiction, shall be replaced by a valid, legal and enforceable provision that best reflects the Parties' intent for such first provision.

14.16 <u>Independent Contractors</u>. Each Party hereby acknowledges that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of the other Party to do so.

14.17 <u>Waiver</u>. The waiver by a Party of any right hereunder, or the failure to perform or of a breach by the other Party, shall not constitute a waiver of any other right hereunder or of any other breach or failure by the other Party whether of a similar nature or otherwise.

14.18 <u>Force Majeure</u>. A Party shall neither be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any obligation under this Agreement to the extent, and for so long as, such failure or delay is caused by, or results from, causes beyond the reasonable control of such Party, regardless of whether such cause is foreseeable as of the Effective Date or thereafter, including fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, national or regional emergency, epidemic or pandemic (including COVID-19), and omissions or delays in acting by any governmental authority or the other Party. [\*\*\*].

#### 14.19 Taxes.

14.19.1 EyePoint will make all payments to Imprimis under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

14.19.2 Any Tax required to be withheld on amounts payable under this Agreement will be paid by EyePoint on behalf of Imprimis to the appropriate governmental authority, and EyePoint shall furnish Imprimis with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by Imprimis.

14.19.3 EyePoint and Imprimis will cooperate with respect to all documentation required by any Taxing authority or reasonably requested by EyePoint to secure a reduction in the rate of applicable withholding Taxes. Promptly after the Effective Date, Imprimis will deliver to EyePoint an accurate and complete Internal Revenue Service Form W-9.

14.20 <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

## [SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

 EYEPOINT PHARMACEUTICALS, INC.

 By:
 /s/ Nancy Lurker

 Name:
 Nancy Lurker

 Title:
 President & CEO

 IMPRIMISRX, LLC
 By:
 /s/ John Saharek

 Name:
 John Saharek

 Title:
 President

# EXHIBIT A

## List of Trademarks

[\*\*\*]

A-1

# <u>EXHIBIT B</u>

## GROUP A CUSTOMERS

[\*\*\*]

**B-1** 

EXHIBIT C

## Group B Customers

[\*\*\*]

## 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: November 9, 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: November 9, 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 September 30, 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: November 9, 2020

/s/ Mark L. Baum

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

Date: November 9, 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.