

**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, 2021

or

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

For the transition period from _____ to _____

Commission File Number: 001-35814

Harrow Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

45-0567010

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

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

37205
(Zip code)

(615) 733-4730

(Registrant's telephone number, including area code)

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
8.625% Senior Notes due 2026	HROWL	The NASDAQ Global Market

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

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

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

As of November 8, 2021, there were 26,902,763 shares of the registrant's common stock, \$0.001 par value, outstanding.

HARROW HEALTH, INC.

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents, including restricted cash of \$200	\$ 57,856	\$ 4,301
Investment in Eton Pharmaceuticals	9,989	28,455
Note receivable - Melt Pharmaceuticals	13,636	-
Accounts receivable, net	4,158	2,662
Inventories	3,925	3,962
Prepaid expenses and other current assets	1,562	1,602
Total current assets	91,126	40,982
Property, plant and equipment, net	4,827	4,453
Operating lease right-of-use assets	4,624	6,799
Intangible assets, net	1,892	1,939
Investment in Surface Ophthalmics	-	1,314
Investment in Melt Pharmaceuticals	-	1,655
Goodwill	332	332
TOTAL ASSETS	\$ 102,801	\$ 57,474
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 7,335	\$ 3,932
Accrued payroll and related liabilities	2,743	2,315
Deferred revenue and customer deposits	3	66
Current portion of paycheck protection program loan payable	-	1,259
Current portion of loan payable, net of unamortized debt discount	-	2,639
Current portion of operating lease liabilities	388	580
Current portion of finance lease obligations	8	8
Total current liabilities	10,477	10,799
Operating lease liabilities, net of current portion	4,621	6,652
Finance lease obligations	12	17
Accrued expenses, net of current portion	-	800
Paycheck protection program loan payable, net of current portion	-	708
Loan payable, net of current portion and unamortized debt discount	71,457	11,670
TOTAL LIABILITIES	86,567	30,646
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Common stock, \$0.001 par value, 50,000,000 shares authorized, 26,902,763 and 25,749,875 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	27	26
Additional paid-in capital	104,551	104,557
Accumulated deficit	(87,989)	(77,400)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY	16,589	27,183
Noncontrolling interests	(355)	(355)
TOTAL EQUITY	16,234	26,828
TOTAL LIABILITIES AND EQUITY	\$ 102,801	\$ 57,474

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Sales, net	\$ 17,811	\$ 14,385	\$ 50,056	\$ 34,244
Other revenues	900	14	2,232	32
Total revenues	18,711	14,399	52,288	34,276
Cost of sales	(4,947)	(3,696)	(13,134)	(10,526)
Gross profit	13,764	10,703	39,154	23,750
Operating expenses:				
Selling, general and administrative	11,356	8,436	28,643	23,806
Research and development	6,125	670	7,142	1,822
Impairment of intangible assets	-	-	-	363
Total operating expenses	17,481	9,106	35,785	25,991
(Loss) income from operations	(3,717)	1,597	3,369	(2,241)
Other (expense) income:				
Interest expense, net	(1,685)	(498)	(3,512)	(1,563)
Equity in losses of unconsolidated entities	(706)	(1,056)	(2,967)	(3,230)
Investment (loss) gain from Eton Pharmaceuticals, net	(2,220)	8,575	(8,639)	2,450
Loss from early extinguishment of loan	-	-	(756)	-
Gain on forgiveness of PPP loan	-	-	1,967	-
Other (expense) income, net	-	5	(51)	24
Total other (expense) income, net	(4,611)	7,026	(13,958)	(2,319)
Total net (loss) income including noncontrolling interests	(8,328)	8,623	(10,589)	(4,560)
Net loss attributable to noncontrolling interest	-	15	-	54
Net (loss) income attributable to Harrow Health, Inc.	\$ (8,328)	\$ 8,638	\$ (10,589)	\$ (4,506)
Preferred dividends and accretion of preferred stock issuance costs	-	-	(472)	-
Net (loss) income attributable to common stockholders	(8,328)	8,638	(11,061)	(4,506)
Basic net (loss) income per share of common stock	\$ (0.31)	\$ 0.33	\$ (0.42)	\$ (0.17)
Diluted net (loss) income per share of common stock	\$ (0.31)	\$ 0.32	\$ (0.42)	\$ (0.17)
Weighted average number of shares of common stock outstanding, basic	27,112,531	25,921,573	26,626,722	25,880,554
Weighted average number of shares of common stock outstanding, diluted	27,112,531	27,090,060	26,626,722	25,880,554

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

HARROW HEALTH, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the period ended September 30, 2021 and 2020
(In thousands, except for share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value					
Balance at June 30, 2020	-	\$ -	25,649,171	\$ 26	\$ 102,889	\$ (87,187)	\$ 15,728	\$ (332)	\$ 15,396
Issuance of common stock in connection with:									
Exercise of employee stock-based options	-	-	2,998	-	(8)	-	(8)	-	(8)
Stock-based payment for services provided			-		-		-		-
Stock-based compensation expense	-	-	-	-	917	-	917	-	917
Net income	-	-	-	-	-	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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value					
Balance at June 30, 2021	-	\$ -	26,893,896	\$ 27	\$ 102,837	\$ (79,661)	\$ 23,203	\$ (355)	\$ 22,848
Issuance of common stock in connection with:									
Exercise of employee stock-based options	-	-	8,867	-	17	-	17	-	17
Stock-based compensation expense	-	-	-	-	1,697	-	1,697	-	1,697
Net loss	-	-	-	-	-	(8,328)	(8,328)	-	(8,328)
Balance at September 30, 2021	-	\$ -	26,902,763	\$ 27	\$ 104,551	\$ (87,989)	\$ 16,589	\$ (355)	\$ 16,234

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value					
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:									
Exercise of employee stock-based options	-	-	3,251	-	(8)	-	(8)	-	(8)
Issuance of common stock related to vesting of RSUs			91,987	-	-	-	-	-	-
Stock-based payment for services provided	-	-	30,000	-	83	-	83	-	83
Stock-based	-	-	-	-	1,995	-	1,995	-	1,995

compensation expense										
Net loss	-	-	-	-	-	(4,506)	(4,506)	(54)	(4,560)	
Balance at September 30, 2020	<u>-</u>	<u>\$ -</u>	<u>25,652,169</u>	<u>\$ 26</u>	<u>\$ 103,798</u>	<u>\$ (78,549)</u>	<u>\$ 25,275</u>	<u>\$ (347)</u>	<u>\$ 24,928</u>	
							Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity	
	Preferred Stock	Par Value	Common Stock	Par Value	Additional Paid-in Capital	Accumulated Deficit				
	Shares		Shares							
Balance at December 31, 2020	-	\$ -	25,749,875	\$ 26	\$ 104,557	\$ (77,400)	\$ 27,183	\$ (355)	\$ 26,828	
Issuance of common stock in connection with:										
Exercise of employee stock-based options	-	-	25,480	-	65	-	65	-	65	
Exercise of warrants	-	-	311,369	-	-	-	-	-	-	
Vesting of RSUs	-	-	1,207,500	1	(1)	-	-	-	-	
Shares withheld related to net share settlement of equity awards	-	-	(391,461)	-	(3,228)	-	(3,228)	-	(3,228)	
Issuance of preferred shares, net of discount and issuance costs	440,000	-	-	-	10,655	-	10,655	-	10,655	
Redemption of preferred shares	(440,000)	-	-	-	(11,000)	-	(11,000)	-	(11,000)	
Payment of preferred dividends	-	-	-	-	(127)	-	(127)	-	(127)	
Stock-based compensation expense	-	-	-	-	3,630	-	3,630	-	3,630	
Net loss	-	-	-	-	-	(10,589)	(10,589)	-	(10,589)	
Balance at September 30, 2021	<u>-</u>	<u>\$ -</u>	<u>26,902,763</u>	<u>\$ 27</u>	<u>\$ 104,551</u>	<u>\$ (87,989)</u>	<u>\$ 16,589</u>	<u>\$ (355)</u>	<u>\$ 16,234</u>	

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

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

	For the Nine Months Ended September 30, 2021	For the Nine Months Ended September 30, 2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss (including noncontrolling interests)	\$ (10,589)	\$ (4,560)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization of property, plant and equipment	1,275	1,377
Amortization of intangible assets	122	127
Amortization of operating lease right-of-use assets	422	550
Provision for bad debt expense	36	221
Amortization of debt issuance costs and discount	480	354
Gain on forgiveness of PPP loan	(1,967)	-
Investment loss from Eton, net	8,639	(2,450)
Equity in losses of unconsolidated entities	2,967	3,230
Interest income paid-in-kind from note receivable	(136)	-
Loss on sale and disposal of assets	-	5
Interest paid-in-kind on loan payable	-	348
Impairment of long-lived assets	-	363
Loss on early extinguishment of loan	706	-
Stock-based payment of consulting services	-	83
Stock-based compensation	3,630	1,995
Changes in assets and liabilities:		
Accounts receivable	(1,532)	(407)
Inventories	37	(673)
Prepaid expenses and other current assets	(866)	(123)
Accounts payable and accrued expenses	2,983	(2,555)
Accrued payroll and related liabilities	428	1,575
Deferred revenue and customer deposits	(63)	6
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	6,572	(534)
CASH FLOWS FROM INVESTING ACTIVITIES		
Net proceeds on sale investments	9,827	-
Issuance of note receivable, Melt Pharmaceuticals	(12,592)	-
Investment in patent and trademark assets	(75)	(111)
Purchases of property, plant and equipment	(1,649)	(780)
NET CASH USED IN INVESTING ACTIVITIES	(4,489)	(891)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on finance lease obligations	(5)	(6)
Net proceeds from 8.625% notes payable, net of costs	71,073	-
Principal and exit fee payments on SWK loan	(15,961)	(750)
Net proceeds from PPP loan payable	-	1,967
Proceeds from SWK debt, net of costs	-	1,000
Payment of taxes upon vesting of RSUs	(3,228)	-
Proceeds from exercise of stock options	65	(8)
Sale of preferred stock, net of discount and issuance costs	10,655	-
Repayment of preferred stock	(11,000)	-
Payment of preferred stock dividends	(127)	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	51,472	2,203
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	53,555	778
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	4,301	4,949
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	\$ 57,856	\$ 5,727
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	\$ 57,656	\$ 5,527
Restricted cash	200	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	\$ 57,856	\$ 5,727
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	\$ -	\$ -
Cash paid for interest	\$ 2,603	\$ 1,222
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Right-of-use asset obtained in exchange for lease obligation	\$ -	\$ 936
Net reduction in right-of-use assets and lease obligations due to modifications	\$ 1,753	\$ -
Issuance of common stock upon vesting of RSUs	\$ 1	\$ -
Melt accounts receivable transferred to note receivable	\$ 908	\$ -

HARROW HEALTH, INC.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the three and nine months ended September 30, 2021 and 2020
(All dollar amounts are expressed 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”) is an ophthalmic-focused healthcare company that 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 non-controlling equity positions in Surface Ophthalmics, Inc. (“Surface”) and Melt Pharmaceuticals, Inc. (“Melt”), both companies that began as subsidiaries of Harrow. In 2020, Harrow created Visionology, Inc. (“Visionology”), which recently launched an online eye health platform business. Harrow also owns royalty rights in various drug candidates being developed by Surface and Melt.

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, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 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, 2020.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned and majority-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Harrow consolidates entities in which it has a controlling financial interest. The Company consolidates subsidiaries in which it holds and/or controls, 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, 2021 and December 31, 2020 and the condensed consolidated statements of operations, stockholders’ equity and cash flows for the periods ended September 30, 2021 and 2020 include our accounts and those of our wholly owned subsidiaries, as well as our majority owned subsidiaries Mayfield Pharmaceuticals, Inc. (“Mayfield”) and Stowe Pharmaceuticals, Inc. (“Stowe”).

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following represents an update for the nine months ended September 30, 2021 to the significant accounting policies described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020.

Risks, Uncertainties and Liquidity

The Company is subject to certain regulatory standards, approvals, guidelines and inspections which could impact the Company’s ability to make, dispense, and sell certain products. If the Company was required to cease compounding and selling certain products as a result of regulatory guidelines or inspections, this may have a material impact on the Company’s financial condition, liquidity and results of operations.

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 of our operating segments. The Company has identified two operating segments as reportable segments. See Note 16 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 loss attributable to noncontrolling interests in consolidated net 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 interest 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 (loss) income per common share is computed by dividing net (loss) income attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net (loss) income per share is computed by dividing the net (loss) income attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period. Common equivalent shares (using the treasury stock method) from stock options, unvested restricted stock units ("RSUs") and warrants were 5,657,046 and 5,447,716 at September 30, 2021 and September 30, 2020, respectively. For the three and nine months ended September 30, 2021 and the nine months ended September 30, 2020, the common equivalent shares are excluded in the calculation of diluted net loss per share because the effect is anti-dilutive. Included in the basic and diluted net (loss) income 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, 2021 and 2020 was 258,117 and 281,507, respectively.

The following table shows the computation of basic and diluted net (loss) income per share of common stock for the three and nine months ended September 30, 2021 and 2020:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator – net (loss) income attributable to Harrow Health, Inc. common stockholders	\$ (8,328)	\$ 8,638	\$ (11,061)	\$ (4,506)
Denominator - weighted average number of shares outstanding, basic	27,112,531	25,921,573	26,626,722	25,880,554
Net (loss) income per share, basic	\$ (0.31)	\$ 0.33	\$ (0.42)	\$ (0.17)

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 (loss) income per share of common stock for the three and nine months ended September 30, 2021 and 2020:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator – net (loss) income attributable to Harrow Health, Inc.	\$ (8,328)	\$ 8,638	\$ (11,061)	\$ (4,506)
Denominator – weighted average number of shares outstanding, basic	27,112,531	25,921,573	26,626,722	25,880,554
Dilutive common equivalent shares	-	1,168,487	-	-
Number of shares used for diluted earnings per share computation	27,112,531	27,090,060	26,626,722	25,880,554
Net (loss) income per share, diluted	\$ (0.31)	\$ 0.32	\$ (0.42)	\$ (0.17)

Investment in Eton Pharmaceuticals, Inc.

During the nine months ended September 30, 2021, the Company sold 1,518,000 shares of its Eton Pharmaceuticals, Inc. (“Eton”) common stock through an underwritten public offering at a public offering price of \$7.00 per share (the “Eton Stock Sale”). The gross proceeds to the Company from the Eton Stock Sale were \$10,626, before deducting underwriting discounts and commissions and other offering expenses payable by the Company of \$799. During the nine months ended September 30, 2021, the Company recorded a realized loss of \$1,406 related to the Eton Stock Sale.

Following the Eton Stock Sale and as of September 30, 2021, the Company owns 1,982,000 shares of Eton common stock, which represents less than 10% of the equity interests of Eton. At September 30, 2021, the fair market value of Eton’s common stock was \$5.04 per share. In accordance with the Accounting Standards Update (“ASU”) 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, the Company recorded an unrealized investment gain (loss) from its Eton common stock position of \$(2,220) and \$(7,233), during the three and nine months ended September 30, 2021, respectively, and \$8,575 and \$2,450 during the three and nine months ended September 30, 2020, respectively, related to the change in fair market value of its investment in Eton during the measurement period. As of September 30, 2021, the fair market value of the Company’s investment in Eton was \$9,989.

As part of the Eton Stock Sale, the Company agreed, for a period of 180 days, not to conduct any further sales of shares of its common stock of Eton or otherwise dispose of, directly or indirectly, any common stock of Eton (or any securities convertible into, or exercisable or exchangeable for, the common stock of Eton).

Investment in Melt Pharmaceuticals, Inc. – Related Party

The Company owns 3,500,000 common shares (which is approximately 46% of the equity interests as of September 30, 2021) of Melt and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Melt. Under this method, the Company recognizes earnings and losses in Melt in its condensed consolidated financial statements and adjusts the carrying amount of its investment in Melt accordingly. The Company’s share of earnings and losses are based on the Company’s ownership interest of Melt. Any intra-entity profits and losses are eliminated. During the three months ended September 30, 2021 and 2020, the Company recorded equity in the net losses of Melt of \$706 and \$300, and \$1,653 and \$1,536 during the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021 and December 31, 2020, the Company’s investment in Melt was \$0 and \$1,655. At September 30, 2021 and December 31, 2020, the Company recorded \$8 and \$851, respectively, due from Melt for reimbursable expenses and amounts due under a Management Services Agreement between the Company and Melt (the “Melt MSA”), which are included in prepaid expenses and other current assets in the accompanying consolidated balance sheets.

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 20% of the equity interests following the close of a round of financing completed by Surface in July 2021) of Surface and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, the Company recognizes earnings and losses in Surface in its condensed consolidated financial statements and adjusts the carrying amount of its investment in Surface accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Surface. Any intra-entity profits and losses are eliminated. The Company recorded equity in the net losses of Surface of \$0 and \$756 during the three months ended September 30, 2021 and 2020, respectively, and \$1,314 and \$1,694 during the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021 and December 31, 2020, the Company's investment in Surface was \$0 and \$1,314, respectively.

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

Impairment of Equity Method Investments and Note Receivable

On a quarterly basis, management assesses whether there are any indicators that the carrying value of the Company's equity method investments and note receivable may be other than temporarily impaired. Indicators include financial condition, operating performance, and near-term prospects of the investee. To the extent indicators suggest that a loss in value may have occurred, the Company will evaluate both quantitative and qualitative factors to determine if the loss in value is other than temporary. If a potential loss in value is determined to be other than temporary, the Company will recognize an impairment loss based on the estimated fair value of the equity method investments and note receivable. At September 30, 2021 and December 31, 2020, no indicators of impairment existed.

Research and Development

Research and development ("R&D") expenses consist of expenses incurred in performing research and development activities, including salaries and benefits, other overhead expenses, and costs related to clinical trials, contract services and outsourced contracts. We expense all costs related to R&D as they are incurred.

Upfront and milestone payments related to the acquisition and licensing of technology for drug and product candidates that are not yet approved by the FDA are considered acquisition of in process R&D and expensed as R&D in the period in which the expense occurs.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes: Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes. This guidance became effective for the Company on January 1, 2021 on a prospective basis. Adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements.

Reclassifications

Certain prior period items and amounts have been reclassified to conform to the classifications used to prepare the consolidated financial statements for the current period. These reclassifications had no material impact on the Company's consolidated financial position, results of operations, or cash flows as previously reported.

NOTE 3. REVENUES

The Company accounts for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers*. The Company has three primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services, (2) revenue recognized from a commission agreement with a third party and (3) revenue 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. Revenue 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 principles 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 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 year ended December 31, 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

As of September 30, 2021, we are party to four intellectual property licenses and asset purchase agreements in which we have agreed to grant a license and which provide a customer with the right to access the Company's intellectual property. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive license rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements can be multiple-element arrangements, the revenue of which is recognized at the point in time at which 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, 2021 and 2020, consists of the following:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Product sales, net	\$ 17,811	\$ 14,385	\$ 50,056	\$ 34,244
Commission revenues	900	-	2,212	-
License revenues	-	14	20	32
Total revenues	\$ 18,711	\$ 14,399	\$ 52,288	\$ 34,276

Deferred revenue and customer deposits at September 30, 2021 and December 31, 2020, were \$3 and \$66, respectively. All deferred revenue and customer deposit amounts at December 31, 2020 were recognized as revenue during the nine months ended September 30, 2021.

NOTE 4. INVESTMENT IN, AND NOTE RECEIVABLE FROM MELT PHARMACEUTICALS, INC. - 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 mid-single-digit royalty payments to the Company on 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. (see Note 2).

Investment in Melt Pharmaceuticals, Inc.

In February 2019, the Company and Melt entered into 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 is required to pay the Company a monthly amount of \$10. As of September 30, 2021 and December 31, 2020, the Company was due \$8 and \$851, respectively, from Melt for reimbursable expenses and amounts due under the Melt MSA. Melt did not make any payments to the Company during the three and nine months ended September 30, 2021. The net funds received by Melt excluded \$908 for amounts owed to the Company for reimbursable expenses and amounts due under the Melt MSA prior to the effective date of the note receivable (see Note 2).

The Company's Chief Executive Officer, Mark L. Baum, was previously a member of the Melt board of directors until his resignation in September 2021. Following Mr. Baum's departure, the Company no longer has any representation on Melt's board of directors.

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

	For the Nine Months Ended September 30,	
	2021	2020
Revenues, net	\$ -	\$ -
Loss from operations	3,907	3,261
Net loss	\$ (3,907)	\$ (3,261)

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

	At September 30, 2021	At December 31, 2020
Current assets	\$ 11,965	\$ 2,947
Non-current assets	-	11
Total assets	11,965	2,958
Total liabilities	14,273	1,778
Total stockholders' (deficit) equity	(2,308)	1,180
Total liabilities and stockholders' equity	\$ 11,965	\$ 2,958

Note Receivable

In September 2021, the Company entered into a loan and security agreement in the principal amount of \$13,500 (the “Melt Loan Agreement”), as lender, with Melt, as borrower. Amounts borrowed under the Melt Loan Agreement bear interest at twelve and one-half percent (12.50%) per annum, which interest can be paid in-kind at the option of Melt until the maturity date. The Melt Loan Agreement permits Melt to pay interest only on the principal amount loaned thereunder through the term and all amounts owed will be due and payable on September 1, 2022. Melt may elect to prepay all, but not less than all, of the amounts owed prior to the maturity date at any time without penalty.

Melt has granted the Company a security interest in substantially all of its personal property, rights and assets, including intellectual property rights, to secure the payment of all amounts owed under the Melt Loan Agreement. The Melt Loan Agreement contains customary representations, warranties and covenants, including covenants by Melt limiting additional indebtedness, liens, mergers and acquisitions, dispositions, investments, distributions, subordinated debt, and transactions with affiliates. The Melt Loan Agreement includes customary events of default, and upon the occurrence of an event of default (subject to cure periods for certain events of default), all amounts owed by Melt thereunder may be declared immediately due and payable by the Company, and the interest rate on the loan may be increased by three percent (3%) per annum.

In connection with the Melt Loan Agreement, the Company and Melt entered into a Right of First Refusal Agreement providing the Company with the right, but not the obligation, to match any offer received by Melt associated with the commercial rights to any of Melt’s drug candidates for a period of five years following the effective date of the Melt Loan Agreement.

The net funds received by Melt excluded \$908 for amounts owed to the Company for reimbursable expenses and amounts due under the Melt MSA prior to the effective date of the note receivable (see Note 2).

NOTE 5. INVESTMENT IN SURFACE OPHTHALMICS, INC. - 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 associated with Surface’s drug candidates (collectively, the “Surface Products”). Surface is required to make mid-single-digit royalty payments to the Company on net sales of the Surface Products while any patent rights remain outstanding.

As of September 30, 2021, the Company owned 3,500,000 shares of Surface common stock (approximately 20% of the equity interests). A Company director, Richard L. Lindstrom, and the Company’s Chief Executive Officer, Mark L. Baum, are directors of Surface. Surface is required to make royalty payments to Dr. Lindstrom of net sales of certain Surface products while certain patent rights remain outstanding. Dr. Lindstrom is also a minority owner of Flying L Partners, an affiliate of the funding investor who purchased the Surface Series A Preferred Stock. Several employees and a director of the Company (including Mr. Baum and Dr. Lindstrom) entered into consulting agreements and provide consulting services to Surface.

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

	For the Nine Months Ended September 30,	
	2021	2020
Revenues, net	\$ -	\$ -
Loss from operations	6,859	5,647
Net loss	<u>\$ (6,859)</u>	<u>\$ (5,647)</u>

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

	At September 30, 2021	At December 31, 2020
Current assets	\$ 25,766	\$ 9,074
Non-current assets	36	45
Total assets	<u>25,802</u>	<u>9,119</u>
Total liabilities	1,836	1,666
Total stockholders' equity	23,966	7,453
Total liabilities and stockholders' equity	<u>\$ 25,802</u>	<u>\$ 9,119</u>

NOTE 6. RESTRICTED CASH

The restricted cash at September 30, 2021 and December 31, 2020 consisted of funds held in a money market account. At September 30, 2021 and December 31, 2020, the restricted cash was recorded at amortized cost, which approximates fair value.

At September 30, 2021 and December 31, 2020, the funds held in a money market account of \$200 were classified as a current asset. The money market account funds are required as collateral as additional security for the Company's New Jersey facility lease.

NOTE 7. 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, 2021 and December 31, 2020 was as follows:

	September 30, 2021	December 31, 2020
Raw materials	\$ 2,108	\$ 2,501
Work in progress	51	17
Finished goods	1,766	1,444
Total inventories	<u>\$ 3,925</u>	<u>\$ 3,962</u>

NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at September 30, 2021 and December 31, 2020, consisted of the following:

	September 30, 2021	December 31, 2020
Prepaid insurance	\$ 1,001	\$ 160
Due from Melt Pharmaceuticals	8	851
Other prepaid expenses	479	401
Deposits and other current assets	74	190
Total prepaid expenses and other current assets	<u>\$ 1,562</u>	<u>\$ 1,602</u>

NOTE 9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at September 30, 2021 and December 31, 2020, consisted of the following:

	September 30, 2021	December 31, 2020
Property, plant and equipment, net:		
Computer software and hardware	\$ 2,494	\$ 1,707
Furniture and equipment	442	418
Lab and pharmacy equipment	4,208	3,426
Leasehold improvements	5,775	5,720
Property, plant and equipment, gross	12,919	11,271
Accumulated depreciation and amortization	(8,092)	(6,818)
	<u>\$ 4,827</u>	<u>\$ 4,453</u>

For the three and nine months ended September 30, 2021, depreciation and amortization related to the property, plant and equipment was \$399 and \$1,275, respectively. For the three and nine months ended September 30, 2020, depreciation and amortization related to property, plant and equipment was \$464 and \$1,377, respectively.

NOTE 10. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at September 30, 2021 consisted of the following:

	Amortization Periods (in years)	Cost	Accumulated Amortization	Impairment	Net Carrying Value
Patents	17-19	\$ 542	\$ (69)	\$ -	\$ 473
Licenses	20	100	(7)	-	93
Trademarks	Indefinite	359	-	-	359
Customer relationships	3-15	1,519	(553)	-	966
Trade name	5	5	(5)	-	-
Non-competition clause	3-4	50	(50)	-	-
State pharmacy licenses	25	8	(7)	-	1
		<u>\$ 2,583</u>	<u>\$ (691)</u>	<u>\$ -</u>	<u>\$ 1,892</u>

Amortization expense for intangible assets for the three and nine months ended September 30, 2021 and 2020 was as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Patents	\$ 8	\$ 6	\$ 20	\$ 25
Licenses	1	-	2	1
Customer relationships	34	33	100	101
Amortization of intangible assets	<u>\$ 43</u>	<u>\$ 39</u>	<u>\$ 122</u>	<u>\$ 127</u>

Estimated future amortization expense for the Company's intangible assets at September 30, 2021 is as follows:

Remainder of 2021	\$ 44
2022	188
2023	188
2024	161
2025	148
Thereafter	804
	<u>\$ 1,533</u>

NOTE 11. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	September 30, 2021	December 31, 2020
Accounts payable	\$ 4,671	\$ 3,645
Other accrued expenses	49	49
Accrued litigation settlement (see Note 15)	1,500	-
Accrued interest	1,115	238
Accrued exit fee for loan payable	-	800
Total accounts payable and accrued expenses	7,335	4,732
Less: Current portion	(7,335)	(3,932)
Non-current total accrued expenses	<u>\$ -</u>	<u>\$ 800</u>

NOTE 12. DEBT

8.625% Senior Notes Due 2026

In April 2021, the Company closed an offering of \$50,000 aggregate principal amount of 8.625% senior notes due in April 2026, and in May 2021 issued an additional \$5,000 of such notes pursuant to the full exercise of the underwriters' option to purchase additional notes (collectively, the "April Notes"). The April Notes were sold to investors at a par value of \$25.00 per April Note and the offering resulted in net proceeds to the Company of approximately \$51,909 after deducting underwriting discounts and commissions and expenses of \$3,091. In June 2021, in a further issuance of the April Notes, the Company sold an additional \$20,000 aggregate principal amount of such notes (the "June Notes," and together with the April Notes, the "Notes"), at a price of \$25.75 per June Note, with interest of \$278 on the June Notes being accrued from April 20, 2021 as of the date of issuance. The June offering resulted in net proceeds to the Company of approximately \$19,164 after deducting underwriting discounts and commissions and expenses of \$1,158 and a premium on note issuance of \$322. The June Notes are treated as a single series with the April Notes under the indenture governing the April Notes, dated as of April 20, 2021, and have the same terms as the April Notes (other than the initial offering price and issue date). The Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of our other existing and future senior unsecured and unsubordinated indebtedness. The Notes are effectively subordinated in right of payment to all of the Company's existing and future secured indebtedness and structurally subordinated to all existing and future indebtedness of the Company's subsidiaries, including trade payables. The Notes bear interest at a rate of 8.625% per annum. Interest on the Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, commencing on July 31, 2021. The Notes will mature on April 30, 2026. The issuance costs were recorded as a debt discount and are being amortized as interest expense, net of the amortization of the premium on note issuance, over the term of the Notes using the effective interest rate method.

Prior to February 1, 2026, the Company may, at its option, redeem the Notes, in whole at any time or in part from time to time, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus a make-whole amount, if any, plus accrued and unpaid interest to, but excluding, the date of redemption. The Company may redeem the Notes for cash in whole or in part at any time at our option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption. On and after any redemption date, interest will cease to accrue on the redeemed Notes.

Interest expense related to the Notes totaled \$1,464 and \$2,930 for the three and nine months ended September 30, 2021, and included amortization of debt issuance costs and discount of \$197 and \$389 for the three and nine months ended September 30, 2021.

SWK Senior Note – Paid in April 2021

In July 2017, the Company and several of its wholly owned subsidiaries 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 were not achieved. The SWK Loan was 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. The SWK Loan bore an interest rate 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 provided 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 had achieved a leverage ratio as of such date of less than 3.00:1.00, the Margin Rate shall equal 7.00%. The leverage ratio means, as of any date of determination, the ratio of: (a) indebtedness as of such date to (b) EBITDA (as defined in the SWK Loan), of the Company for the immediately preceding 12 month period, adding-back (i) actual litigation expenses for the immediately preceding 12 month period, minus (ii) actual litigation expenses for the immediately preceding 3 month period multiplied by 4.

A summary of the material changes contained in the amendment entered into with SWK in April 2020 was 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 Second Amendment; and
- The interest payment of \$358 due May 14, 2020 was paid in-kind by increasing the principal amount of the term loans by an amount equal to the interest accrued as of such date.

Interest expense related to the SWK Loan Agreement, as amended, amounted to \$0 and \$647 for the three and nine months ended September 30, 2021, respectively, and \$501 and \$1,566 for the three and nine months ended September 30, 2020, respectively, and included amortization of debt issuance costs and discounts of \$0 and \$96 for the three and nine months ended September 30, 2021, respectively, and \$111 and \$354 for the three and nine months ended September 30, 2020, respectively.

In April 2021, the Company paid \$15,540 related to all outstanding obligations to SWK under the SWK Loan, including outstanding principal, accrued interest, accrued exit fee and related expenses and recorded a loss from early extinguishment of \$756 related to the SWK Loan during the nine months ended September 30, 2021.

Paycheck Protection Program Loan – Forgiven in March 2021

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 (the “SBA”). On March 30, 2021, the Company received a notice of forgiveness of the full balance of the PPP Loan, including all accrued interest, in accordance with the terms and conditions of the CARES Act. Related to the forgiveness, the Company recorded a gain on the forgiveness of the PPP Loan for the loan balance of \$1,967 in the accompanying condensed consolidated statement of operations for the nine months ended September 30, 2021.

At September 30, 2021, future minimum payments under the Company’s debt were as follows:

	Amount
Remainder of 2021	\$ 2,769
2022	6,562
2023	6,562
2024	6,580
2025	6,562
2026	77,158
Total minimum payments	106,193
Less: amount representing interest payments	(31,193)
Notes payable, gross	75,000
Less: unamortized discount, net of premium	(3,543)
Notes payable, net of unamortized discount	\$ 71,457

NOTE 13. LEASES

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

- An operating lease for 10,200 square feet of office space in San Diego, California that expires in December 2021;
- 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 another amendment entered into in May 2021 that extended the term of the lease to July 2027; 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.

In May 2021, the Company amended its New Jersey lease to include the addition of 8,926 square feet of space (the “May Lease Amendment”), which will expire in July 2027. The Company expects to take possession of this additional space in November 2021, which will trigger the commencement of the May Lease Amendment. Since the commencement date of the May Lease Amendment is expected to occur after September 30, 2021, right-of-use assets and operating lease liabilities associated with the May Lease Amendment are not included in the Company’s condensed consolidated balance sheet as of September 30, 2021.

In May 2021, the Company entered into an operating lease for 5,789 square feet of office space (the “1000 Aviara Lease”) in Carlsbad, California, which will expire in March 2025. The Company expects to take possession of this space in December 2021, which will trigger the commencement of the 1000 Aviara Lease. Since the commencement date of the 1000 Aviara Lease is expected to occur after September 30, 2021, right-of-use assets and operating lease liabilities associated with the 1000 Aviara Lease is not included in the Company’s condensed consolidated balance sheet as of September 30, 2021.

At September 30, 2021, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 6.32% and 14.18 years, respectively.

During the three and nine months ended September 30, 2021, cash paid for amounts included for the operating lease liabilities was \$250 and \$752, respectively, and the Company recorded operating lease expense of \$203 and \$705, included in selling, general and administrative expenses, respectively.

Future lease payments under operating leases as of September 30, 2021 were as follows:

	Operating Leases
Remainder of 2021	\$ 251
2022	585
2023	600
2024	617
2025	433
Thereafter	5,146
Total minimum lease payments	7,632
Less: amount representing interest payments	(2,623)
Total operating lease liabilities	5,009
Less: current portion, operating lease liabilities	(388)
Operating lease liabilities, net of current portion	\$ 4,621

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

Future lease payments under the non-cancelable finance lease as of September 30, 2021 were as follows:

	Finance Leases
Remainder of 2021	\$ 2
2022	9
2023	9
2024	1
Total minimum lease payments	21
Less: amount representing interest payments	(1)
Present value of future minimum lease payments	20
Less: current portion, finance lease obligation	(8)
Finance lease obligation, net of current portion	\$ 12

At September 30, 2021, the incremental borrowing rate and the remaining lease term for the finance lease held by the Company were 6.36% and 2.33 years, respectively.

For the three and nine months ended September 30, 2021, 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, 2021, cash paid and expense recognized for interest expense related to the finance lease obligation was \$0 and \$1, respectively.

NOTE 14. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Preferred Stock

At September 30, 2021 and 2020, the Company had 5,000,000 shares of preferred stock, \$0.001 par value, authorized and no shares of preferred stock issued and outstanding.

Series B Cumulative Preferred Stock – Redeemed in June 2021

In May 2021, the Company sold 440,000 shares of the Company's Series B Cumulative Preferred Stock, par value \$0.001 per share and liquidation preference of \$25.00 per share (the "Series B Preferred Stock"), for net proceeds of approximately \$10,655. The Series B Preferred Stock was not convertible into our common stock, had no voting rights, except as required by Delaware law, and was redeemable by the Company at any time. Holders of Series B Preferred Stock were entitled to cumulative cash dividends at the rate of 9.50% of the \$25.00 liquidation preference per year; provided, however, that for each thirty (30) day period following May 5, 2021, the dividend rate increased at various rates, except as otherwise limited by applicable law. Dividends were payable quarterly in arrears, on or about the 15th of January, April, July and October, beginning on or about July 15, 2021.

In June 2021, the Company redeemed all of the outstanding shares of the Series B Preferred Stock. The redemption price for the 440,000 shares of Series B Preferred Stock outstanding was equal to \$25.00 per share, plus accrued and unpaid dividends, which in aggregate totaled \$11,127. During the three and nine months ended September 30, 2021, the Company recorded preferred stock cash dividends and deemed dividends equal to \$0 and \$472, respectively.

Common Stock

During the nine months ended September 30, 2021, the Company issued 311,369 shares of its common stock upon the cashless exercise of warrants to purchase 406,539 shares of common stock with exercise prices between \$1.79 and \$3.75 per share.

During the nine months ended September 30, 2021, the Company issued 25,480 shares of its common stock upon the exercise of options to purchase 25,480 shares of common stock with exercise prices between \$1.70 and \$4.29 per share and received net proceeds of \$65.

During the nine months ended September 30, 2021, the Company issued 715,871 shares of its common stock to Mark L. Baum, its Chief Executive Officer, related to the vesting of 1,050,000 performance-based restricted stock units. The Company withheld issuance of 334,129 shares of common stock valued at \$2,760 for payroll tax purposes.

During the nine months ended September 30, 2021, the Company issued 100,168 shares of common stock to Andrew R. Boll, its Chief Financial Officer, related to the vesting of 157,500 performance-based restricted stock units. The Company withheld issuance of 57,332 shares of common stock to Mr. Boll for payroll tax purposes valued at \$468.

During the nine months ended September 30, 2021, 57,654 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 applicable director resigns.

Stock Option Plan

On September 17, 2007, the Company's Board of Directors and stockholders adopted the Company's 2007 Incentive Stock and Awards Plan, which was subsequently amended on November 5, 2008, February 26, 2012, July 18, 2012, May 2, 2013 and September 27, 2013 (as amended, the "2007 Plan"). The 2007 Plan reached its term in September 2017, and we can no longer issue additional awards under this plan, however, options previously issued under the 2007 Plan will remain outstanding until they are exercised, reach their maturity or are otherwise cancelled/forfeited. On June 13, 2017, the Company's Board of Directors and stockholders adopted the Company's 2017 Incentive Stock and Awards Plan which was subsequently amended on June 3, 2021 (as amended, the "2017 Plan" together with the 2007 Plan, the "Plans"). As of September 30, 2021, the 2017 Plan provides for the issuance of a maximum of 6,000,000 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 of 1986, as amended, 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 2,400,592 shares available for future issuances under the 2017 Plan at September 30, 2021.

Stock Options

A summary of stock option activity under the Plans for the three and nine months ended September 30, 2021 is as follows:

	Number of Shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding – January 1, 2021	3,030,033	\$ 5.43		
Options granted	77,000	\$ 8.13		
Options exercised	(25,480)	\$ 2.62		
Options cancelled/forfeited	(41,199)	\$ 5.88		
Options outstanding – September 30, 2021	<u>3,040,354</u>	\$ 5.52	5.03	\$ 10,868
Options exercisable	<u>2,403,938</u>	\$ 5.07	4.71	\$ 9,672
Options vested and expected to vest	<u>2,976,713</u>	\$ 5.48	5.00	\$ 10,748

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 shares underlying options with an exercise price lower than the market price on September 30, 2021, based on the closing price of the Company's common stock of \$9.09 on that date.

During the nine months ended September 30, 2021, 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, 2021, generally included 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. 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.

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 factor 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 using the Black-Scholes-Merton option pricing model with the following assumptions used for valuing options granted to employees:

	2021
Weighted-average fair value of options granted	\$ 5.25
Expected terms (in years)	5-6.11
Expected volatility	69-74%
Risk-free interest rate	0.39-0.45%
Dividend yield	-

The following table summarizes information about stock options outstanding and exercisable at September 30, 2021:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$1.47 - \$2.60	751,763	4.86	\$ 2.06	751,350	\$ 2.06
\$2.76 - \$4.66	505,000	4.96	\$ 3.99	454,621	\$ 3.98
\$5.49 - \$6.36	470,350	6.34	\$ 6.12	384,482	\$ 6.14
\$6.64 - \$8.99	1,313,241	4.68	\$ 7.87	813,485	\$ 7.95
\$1.47 - \$8.99	<u>3,040,354</u>	5.03	\$ 5.52	<u>2,403,938</u>	\$ 5.07

As of September 30, 2021, there was approximately \$1,656 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 5.25 years. The stock-based compensation for all stock options was \$355 and \$1,376 during the three and nine months ended September 30, 2021, respectively.

The intrinsic value of options exercised during the three and nine months ended September 30, 2021 was \$69 and \$146, respectively.

Restricted Stock Units/ Performance 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, 2021, 300,000 RSUs with a fair market value of \$2,670 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.

During the nine months ended September 30, 2021, the Company's board of directors were granted 38,576 RSUs with a fair market value of \$400, which vest in equal quarterly installments over one year.

During the three and nine months ended September 30, 2021, the Company granted 1,567,913 performance stock units ("PSUs") to members of its senior management including Mark Baum, Chief Executive Officer, Andrew Boll, Chief Financial Officer, and John Saharek, President of ImprimisRx, which are subject to the satisfaction of certain market-based and continued service conditions (the "2021 PSUs"). The 2021 PSUs are separated into four tranches and require that the Company achieve and maintain certain levels of total stockholder returns ("TSR") ranging from 50% to 175% per share during the five-year period following the grant date. TSR is based on the aggregate of: (i) the percent increase of the closing price of the Company's common stock from July 22, 2021; and (ii) any dividends or like stockholder distributions as specified in the table below. With certain limited exceptions, in addition to reaching the TSR targets, the employee must be employed with the Company on the second anniversary of the grant date in order for the 2021 PSUs to vest.

Tranche	Number of Shares	TSR	Target Share Price*
Tranche 1	223,988	50% or greater	\$ 11.70
Tranche 2	335,981	100% or greater	\$ 15.60
Tranche 3	447,975	150% or greater	\$ 19.50
Tranche 4	559,969	175% or greater	\$ 21.45

*Target Share Price assumes that no dividends or like distributions are made to shareholders of the Company. If such distributions are made, the Target Share Price would decrease accordingly, to the benefit of the employee, to account for the dividend/distribution as a part of TSR.

The fair value of the 2021 PSUs was \$10,113 using a Monte Carlo Simulation with a five-year life, 75% volatility and a risk free interest rate of 0.72%. This amount is being amortized over a two-year derived service period.

A summary of the Company's RSU activity (including PSUs) and related information for the nine months ended September 30, 2021 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested - January 1, 2021	1,601,509	\$ 3.14
RSUs granted	1,906,489	\$ 6.91
RSUs vested	(1,265,153)	\$ 2.34
RSUs cancelled/forfeited	-	-
RSUs unvested at September 30, 2021	<u>2,242,845</u>	<u>\$ 6.80</u>

As of September 30, 2021, the total unrecognized compensation expense related to unvested RSUs was approximately \$12,379, which is expected to be recognized over a weighted-average period of 1.73 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, 2021 was \$1,340 and \$2,167, respectively.

Warrants

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

A summary of warrant activity for the nine months ended September 30, 2021 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted Average Exercise Price
Warrants outstanding - January 1, 2021	780,386	\$ 2.12
Granted	-	
Exercised	(406,539)	2.16
Expired	-	
Warrants outstanding and exercisable - September 30, 2021	<u>373,847</u>	<u>\$ 2.08</u>
Weighted average remaining contractual life of the outstanding warrants in years - September 30, 2021	<u>2.8</u>	

Warrants outstanding and exercisable as of September 30, 2021 are as follows:

Warrant Series	Issue Date	Warrants Outstanding	Exercise Price	Expiration Date
Lender warrants	7/19/2017	373,847	\$ 2.08	7/19/2024

Subsidiary Stock-Based Transactions

The Company recognized \$2 and \$87 in stock-based compensation expense related to subsidiary stock options during the three and nine months ended September 30, 2021, respectively.

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 September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Employees - selling, general and administrative	\$ 1,435	\$ 740	\$ 2,984	\$ 1,612
Employees - R&D	144	-	328	-
Directors - selling, general and administrative	118	177	318	370
Consultants - selling, general and administrative	-	-	-	96
Total	<u>\$ 1,697</u>	<u>\$ 917</u>	<u>\$ 3,630</u>	<u>\$ 2,078</u>

NOTE 15. COMMITMENTS AND CONTINGENCIES

Legal

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 for the District of Delaware asserting various claims, including 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 claims related to its purported termination of the asset purchase agreement. In October 2019, NDS voluntarily dismissed all but two claims, leaving only claims related to the scope and performance of the post-termination obligations to be litigated. On November 8, 2021, following a jury trial, the Company and NDS entered into a voluntary settlement agreement (the “Settlement Agreement”) to resolve all claims and pending matters related to this lawsuit. The Company estimates the Settlement Agreement will result in a single one-time payment of \$1,500 to NDS. Except for the one-time payment, the Company does not expect the Settlement Agreement will have any future material impact on the Company’s consolidated cash flows, financial position, and results of operations. As of September 30, 2021, the Company had accrued an estimate of \$1,500 in selling, general and administrative expenses owed to NDS as a result of the Settlement Agreement.

Product and Professional Liability

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

John Erick et al.

In January 2018, John Erick and Deborah Ferrell, successors-in-interest and heirs of Jade Erick, (collectively “Erick”) filed a lawsuit in the San Diego County Superior Court 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 sought indemnity and contribution from the Company and Spectrum. In November 2021, the lawsuit involving the Company was resolved. There was no impact to the Company’s consolidated financial position and results of operations as a result of the resolution of the case for the Company.

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, 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 designed to protect and rehabilitate the ocular surface (the "Klarity Product").

Under the terms of the Klarity License Agreement, the Company is required to make royalty payments to Dr. Lindstrom ranging from 3% - 6% of net sales, dependent upon the final formulation of the Klarity Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including: (i) an initial payment of \$50 upon execution of the Klarity License Agreement, (ii) a second payment of \$50 following the first \$50 in net sales of the Klarity Product; and (iii) a final payment of \$50 following the first \$100 in net sales of the Klarity Product. All of the above referenced milestone payments are payable at the Company's election in cash or shares of the Company's restricted common stock. Payments totaling \$44 and \$114 were made during the three and nine months ended September 30, 2021, respectively. Payments totaling \$0 and \$55 were made during the three and nine months ended September 30, 2020, respectively. Royalty expense of \$51 and \$130 was incurred during the three and nine months ended September 30, 2021, respectively, and \$51 is included in accounts payable to Dr. Lindstrom as of September 30, 2021. Royalty expense of \$38 and \$94 was incurred during the three and nine months ended September 30, 2020, respectively.

Injectable Asset Purchase Agreement – Related Party

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

Under the terms of the Lindstrom APA, the Company is required to make royalty payments to Dr. Lindstrom ranging from 2% to 3% of net sales, dependent upon the final formulation and patent protection of the Lindstrom Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including an initial payment of \$33 upon execution of the Lindstrom APA. Dr. Lindstrom was paid \$7 and \$21 in cash during the three and nine months ended September 30, 2021, respectively. Dr. Lindstrom was paid \$0 and \$7 in cash during the three and nine months ended September 30, 2020, respectively. The Company incurred royalty expense of \$7 and \$21 and \$6 and \$48 related to the Lindstrom APA during the three and nine months ended September 30, 2021, and 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[®] (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 DEXYCU 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 DEXYCU in the U.S.

The Dexycu Agreement expires on August 1, 2025, subject to early termination in accordance with the terms set forth therein. Either party may terminate the Dexycu Agreement, subject to specified notice periods and limitations, in the event of (i) uncured material breach by the other party or (ii) if DEXYCU 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, 2021, the Company recorded \$900 and \$2,212, respectively, 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 and non-exclusive sales and marketing representation services to Harrow in select geographies in the U.S. in connection with the Company’s ophthalmic pharmaceutical compounded formulations or related products.

Under the terms of the sales and marketing agreements, the Company is generally required to make commission payments equal to 10% - 14% of net sales for products above and beyond the initial existing sales amounts. In addition, the Company is required to make periodic milestone payments to certain organizations in shares of the Company’s restricted common stock if net sales in the assigned territory reach certain future levels by the end of their terms. Commission expenses of \$953 and \$2,766 and \$741 and \$1,745 were incurred under these agreements during the three and nine months ended September 30, 2021, and 2020, respectively.

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 new drug application with the FDA for the first product arising from the acquired intellectual property (if any); and (4) certain royalty payments based on the net receipts received by the Company in connection with the sale or licensing of any product based on the acquired intellectual property (if any), after deducting (among other things) the Company’s development costs associated with such product. If, following five years after the date of the applicable asset purchase agreement, the Company either (a) for certain of the Inventors, has not filed an IND or, for the remaining Inventors, has not initiated a study where data is derived, or (b) has failed to generate royalty payments to the Inventors for any product based on the acquired intellectual property, the Inventors may terminate the applicable asset purchase agreement and request that the Company re-assign the acquired technology to the Inventors. Royalty expenses of \$285 and \$778 and \$159 and \$420 were incurred under these agreements for the three and nine months ended September 30, 2021 and 2020, respectively, and \$285 and \$590 are included in accounts payable at September 30, 2021 and 2020, respectively.

Mayfield Pharmaceuticals MAY-66 License Termination

In May 2021, Mayfield terminated the License Agreement (the “TGV License”) with TGV-Health, LLC and affiliated entities (collectively, “TGV”), pursuant to which it acquired intellectual property rights for use in the women’s health field, related to Mayfield’s proprietary drug candidate MAY-66. Concurrent with the termination, TGV returned to Mayfield 300,000 shares of Mayfield’s common stock, constituting all of the equity held by TGV. Mayfield has no outstanding or remaining obligations under the TGV License.

Mayfield Pharmaceuticals MAY-44 APA Termination

In May 2021, Mayfield and Harrow terminated their asset purchase agreement dated January 2020 (the “MAY-44 APA”) for intellectual property rights associated with Mayfield’s drug candidate MAY-44 with Elle Pharmaceutical LLC (“Elle”). As part of the termination, Mayfield re-acquired 350,000 shares of its common stock from Elle. Mayfield has no outstanding or remaining obligations related to the MAY-44 APA.

Stowe License Termination

In May 2021, Stowe terminated the License Agreement (the “Stowe License”) with TGV, pursuant to which it acquired intellectual property rights for use in the ophthalmic field, related to Stowe’s proprietary drug candidate STE-006. Concurrent with the termination, TGV returned to Stowe 1,750,000 shares of Stowe’s common stock, constituting all of the equity held by TGV. Stowe has no outstanding or remaining obligations under the Stowe License.

Sintetica Agreement

In July 2021, the Company entered into a License and Supply Agreement (the “Sintetica Agreement”) with Sintetica S.A. (“Sintetica”), pursuant to which Sintetica granted the Company the exclusive license and marketing rights to its patented ophthalmic drug candidate (“AMP-100”) in the U.S. and Canada.

Pursuant to the Sintetica Agreement, the Company will pay Sintetica a per unit transfer price to supply AMP-100, along with a per unit royalty for units sold. The Company is required to pay Sintetica up to \$18,000 in one-time milestone payments including a \$5,000 payment (the “Upfront Payment”) due within 30 days of signing the Sintetica Agreement and the balance of payments due upon achievement of certain regulatory and commercial milestones. Under the terms of the Sintetica Agreement, Sintetica will be responsible for regulatory filings for AMP-100 in the U.S. The Upfront Payment was paid and recorded as R&D expense during the three and nine months ended September 30, 2021.

Subject to certain limitations, the term of the Sintetica Agreement is ten years, and allows for a ten-year extension if certain sales thresholds are met.

Wakamoto Agreement

In August 2021, the Company entered into a License Agreement and a Basic Sale and Purchase Agreement (together, the “Wakamoto Agreements”) with Wakamoto Pharmaceutical Co., Ltd. (“Wakamoto”), pursuant to which Wakamoto granted the Company the exclusive license and marketing rights to its ophthalmic drug candidate (“MAQ-100”) in the U.S. and Canada.

Pursuant to the Wakamoto Agreements, Wakamoto will supply MAQ-100 to the Company, and the Company will pay Wakamoto a per unit transfer price to supply MAQ-100. In addition, the Company is required to pay Wakamoto various one-time milestone payments totaling up to \$2,000 upon the achievement of certain regulatory milestones and up to \$6,200 upon the achievement of certain commercial milestones. Under the terms of the Agreements, the Company will be responsible for regulatory filings and fees for MAQ-100 in the U.S. and Canada. Through September 30, 2021, no amounts have been paid or accrued under the Wakamoto agreement.

Subject to certain limitations, the term of the Agreements is for five years from the date of the FDA’s market approval of MAQ-100 and allows for a five-year extension if certain unit sales thresholds are met.

NOTE 16. 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 business known as ImprimisRx; and (ii) its start-up operations associated with its 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, commissions 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, 2021 and 2020:

	For the Three Months Ended September 30, 2021		
	ImprimisRx	Pharmaceutical Drug Development	Total
Net revenues	\$ 18,711	\$ -	\$ 18,711
Cost of sales	(4,947)	-	(4,947)
Gross profit	13,764	-	13,764
Operating expenses:			
Selling, general and administrative	6,726	-	6,726
Research and development	475	5,290	5,765
Segment contribution	\$ 6,563	\$ (5,290)	1,273
Corporate			4,587
Research and development			360
Amortization			43
Operating loss			\$ (3,717)

	For the Nine Months Ended September 30, 2021		
	ImprimisRx	Pharmaceutical Drug Development	Total
Net revenues	\$ 52,288	\$ -	\$ 52,288
Cost of sales	(13,134)	-	(13,134)
Gross profit	39,154	-	39,154
Operating expenses:			
Selling, general and administrative	18,919	-	18,919
Research and development	797	5,407	6,204
Segment contribution	\$ 19,438	\$ (5,407)	14,031
Corporate			9,602
Research and development			938
Amortization			122
Operating income			\$ 3,369

For the Three Months Ended September 30, 2020			
	ImprimisRx	Pharmaceutical Drug Development	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

For the Nine Months Ended September 30, 2020			
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	\$ 34,276	\$ -	\$ 34,276
Cost of sales	(10,526)	-	(10,526)
Gross profit	23,750	-	23,750
Operating expenses:			
Selling, general and administrative	17,131	131	17,262
Research and development	634	79	713
Segment contribution	\$ 5,985	\$ (210)	5,775
Corporate			6,417
Research and development			1,109
Amortization			127
Asset sales and impairments, net			363
Operating loss			\$ (2,241)

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, 2021 and December 31, 2020 were located in the U.S.

Concentrations

The Company has two products that each comprised more than 10% of total revenues during the quarter. These products collectively accounted for 35% of revenues during each of the three and nine months ended September 30, 2021.

The Company sells its compounded formulations to a large number of customers. There were no customers who comprised more than 10% of the Company's total pharmacy sales for the three and nine months ended September 30, 2021 and 2020.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 59% and 71% of active pharmaceutical ingredient purchases during the three and nine months ended September 30, 2021, respectively, and 76% and 72% of active pharmaceutical ingredient purchases during the three and nine months ended September 30, 2020, respectively.

NOTE 17. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to September 30, 2021 through the filing date of this Quarterly Report. Based on its evaluation, no events other than those described in the notes hereto need to be disclosed.

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, 2020 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; 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 SEC. 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

We are an ophthalmic-focused healthcare company. 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 Surface Ophthalmics, Inc. (“Surface”) and Melt Pharmaceuticals, Inc. (“Melt”), both companies that began as subsidiaries of Harrow. In 2020, Harrow created Visionology, Inc. (“Visionology”) and recently launched an online eye health platform business in certain regions. We also own royalty rights in various drug candidates being developed by Surface and Melt.

ImprimisRx

ImprimisRx is our ophthalmology focused prescription pharmaceutical business. We offer to over 10,000 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 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”).

On August 1, 2020, 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® (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint pays ImprimisRx a fee that is calculated based on the quarterly sales of DEXYCU in excess of predefined volumes to specific customers of ImprimisRx in the U.S.

AMP-100

Sintetica has granted the Company the exclusive license and marketing rights to AMP-100 in the U.S. and Canada. AMP-100 is a patented, ophthalmic topical anesthetic drug candidate. If FDA-approved, the active ingredient used in AMP-100 will be the first approved use of this active ingredient in the U.S. ophthalmic market.

The safety and efficacy of AMP-100 was demonstrated in various clinical trials including a Phase 2/3 randomized, double-masked, vehicle-controlled, efficacy, safety and tolerability study in healthy volunteers and a non-inferiority Phase 3 study of 342 patients undergoing cataract surgeries comparing AMP-100 to an active comparator. Ultimately, these studies demonstrated:

- AMP-100 is safe, and the most common adverse event was mydriasis (dilation of pupil) in about 20% of patients which is an effect most ophthalmologists may consider beneficial;
- AMP-100 has rapid onset, and no inferiority to the active comparator (Phase 3);
- Anesthesia success of patients receiving AMP-100 was 95% vs. 20% with placebo (Phase 2/3 study);
- Single administration of AMP-100 provides roughly 20 minutes of sensory loss; and
- AMP-100 has predictable offset (end of anesthesia) within a narrow bell curve (i.e. no wide variance).

We expect a new drug application (“NDA”) for AMP-100 to be submitted by Sintetica to the FDA in the fourth quarter of 2021 and, if approved, we plan to commercially launch AMP-100 in the fourth quarter of 2022.

If approved, we expect our initial commercial focus of AMP-100 to be on ophthalmic procedures that traditionally require the eye to be anesthetized. According to a 2019 MarketScope report, there are over four million cataract surgeries performed in the U.S. annually. In addition to cataract procedures, according to Ophthalmologica, there were about 5.9 million intravitreal injections performed in the U.S. in 2018. Most of these intravitreal injections, which are typically treatments for a variety of conditions, including age-related macular degeneration, diabetic macular edema, and uveitis, often require the ocular surface to be anesthetized during the procedure.

AMP-100 is protected by one issued patent and another patent-pending. The issued patent includes composition of matter and method of use claims and could provide protection for AMP-100 into 2037.

In addition to AMP-100, we expect to acquire and/or develop additional FDA-approved/approvable ophthalmic products and product candidates that will allow us to leverage the commercial infrastructure of ImprimisRx to promote, sell, and ultimately bring these products to market.

MAQ-100

In August 2021, we obtained the exclusive license and marketing rights to MAQ-100 in the U.S. and Canada from Wakamoto Pharmaceutical Co., Ltd. (“Wakamoto”). MAQ-100 is a preservative-free triamcinolone acetonide ophthalmic injection drug candidate. MAQ-100 is marketed and sold by Wakamoto in Japan as MaQaid®. Following Japan’s Ministry of Health Labor and Welfare (“MHLW”) approval, MaQaid was launched in Japan in 2010, indicated as an intravitreal injection for visualization for vitrectomy. Since its initial MHLW approval, the indication for MaQaid was expanded to include (a) treatments for alleviation of diabetic macular edema, (b) macular edema associated with retinal vein occlusion (or RVO), and (c) non-infectious uveitis. We intend to leverage the clinical data used for Japanese market approval of MaQaid to support a clinical program and U.S. market NDA submission of MAQ-100 for visualization during vitrectomy. We intend to request a meeting with FDA during the first half of 2022 to discuss our planned clinical program for MAQ-100.

We expect to acquire and/or develop additional FDA-approved/approvable ophthalmic products and product candidates that will allow us to leverage the commercial infrastructure of ImprimisRx to promote, sell, and ultimately bring these products to market.

Visionology

Visionology, a direct-to-consumer online eye health platform, leverages our experience in the ophthalmic pharmaceutical business as well as our relationships with eyecare professionals across the United States. We recently launched a proof-of-concept model for Visionology within a certain region of the U.S., and if successful, will expand the launch on a nationwide basis in 2022.

Pharmaceutical Compounding Businesses

Pharmaceutical Compounding

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

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

Our Compounding Facilities

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

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

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

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

Pharmaceutical Development - Carve-Out Businesses

We have ownership interests in Eton Pharmaceuticals, Inc. ("Eton"), Surface and Melt and hold royalty interests in some of the drug candidates of Surface and Melt. These companies are pursuing market approval for their drug candidates under the FDCA, including in some instances under the abbreviated pathway described in Section 505(b)(2) which permits the submission of a new drug application ("NDA") where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

In 2018 and 2019, we formed and created subsidiaries named Radley Pharmaceuticals, Inc. (“Radley”), Mayfield Pharmaceuticals, Inc. (“Mayfield”), and Stowe Pharmaceuticals, Inc. (“Stowe”). In 2020, we halted nearly all operating activities related to these subsidiaries to invest resources in other areas, and we may not restart any or all activities related to these businesses. In addition, we terminated license and acquisition agreements for Mayfield’s MAY-66 and MAY-44 drug candidates, and Stowe’s STE-006 drug candidate.

Noncontrolling Equity Interests (De-Consolidated Businesses)

Surface Ophthalmics, Inc.

Surface is a clinical-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases.

In January 2021, Surface announced positive top-line results from a phase 2 trial of its drug candidate SURF-201, a 0.2% betamethasone, preservative-free ophthalmic solution in the Klarity delivery vehicle for the treatment of post cataract surgery pain and inflammation. According to the Surface results, SURF-201 was dosed twice daily, met its primary endpoints of absence of inflammation at both Day 8 and Day 15 and was found to be safe and well-tolerated by the patient group. In addition, a secondary endpoint showed almost 90% of patients given SURF-201 were pain free at Day 15. SURF-201 marks the first ophthalmic therapeutic in the United States to utilize betamethasone and the first preservative-free unit dose therapy for the treatment of post-operative pain and inflammation.

Also in January 2021, Surface announced the first patient dosed in a head-to-head phase 2 trial for its drug candidate SURF-100 (mycophenolate sodium and betamethasone in Klarity vehicle) for the treatment of chronic dry eye disease. The head-to-head study will compare SURF-100 against leading on-market competitors lifitegrast ophthalmic solution 5% (marketed as Xiidra®) and cyclosporine ophthalmic emulsion 0.05% (marketed as Restasis®).

In February 2021, Surface announced the first patient dosed in a phase 2 trial for its drug candidate SURF-200 (betamethasone in Klarity vehicle) for the treatment of episodic dry eye flares. The dose ranging study for SURF-200 will be administered in two different low concentration formulations of betamethasone in the Klarity vehicle. The trial will enroll 120 to 140 patients with a primary endpoint of Symptom Improvement of one unit based on the University of North Carolina Dry Eye Management Scale by the eighth day.

In 2018, Surface closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements. During May, June and July of 2021, Surface closed an offering of its preferred stock at a purchase price of \$4.50 per share resulting in gross proceeds to Surface of approximately \$25,000,000 (the “Surface Series B Offering”). We own 3,500,000 shares of Surface common stock which was approximately 20% of the equity and voting interests following the final closing of the Surface Series B Offering. Harrow owns mid-single digit royalty rights on net sales of SURF-100, SURF-200 and SURF-201.

Melt Pharmaceuticals, Inc.

Melt is a clinical-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”), pursuant to which Harrow assigned to Melt the underlying intellectual property for Melt’s current pipeline, including its lead drug candidate MELT-300. The core intellectual property Melt owns is a patented series of combination non-opioid sedation drug formulations that we estimate to have multitudinous applications.

MELT-300 is a novel, sublingually delivered, non-IV, opioid-free drug candidate being developed for procedural sedation. Melt filed an investigational new drug application (“IND”) with the FDA in June 2020 and began its clinical program for MELT-300. In February 2021, Melt announced data from, and the successful completion of, its phase 1 study. Melt recently began enrolling patients in its phase 2 study for MELT-300.

In January 2019, Melt closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Melt from our consolidated financial statements. We own 3,500,000 shares of Melt common stock, which was approximately 46% of the equity and voting interests issued and outstanding of as of September 30, 2021. In September 2021, we provided Melt with a senior secured loan in the amount of \$13,500,000, which is intended to fund the Phase 2 program of MELT-300. In connection with the loan we provided Melt, we also were provided the right, but not the obligation, to match any offer received by Melt associated with the commercial rights to any of its drug candidates for a period of five years. Melt is required to make mid-single digit royalty payments to the Company on net sales of MELT-300, while any patent rights remain outstanding, subject to other conditions. Melt can require the Company to cease compounding like products at the time of FDA approval of MELT-300. If approved, we do not expect a cessation of compounding like products to have a material impact on our operations and financial performance.

Eton is a commercial-stage pharmaceutical company focused on developing and commercializing innovative drug products. Its pipeline includes several products and drug candidates in various stages of development across a variety of dosage forms. In May 2017, Eton closed an offering of its Series A Preferred Stock and we gave up our controlling interest in it. In November 2018, Eton completed an initial public offering of its common stock. As of the date of this Quarterly Report and following our April 2021 sale, we own 1,982,000 shares of Eton common stock. We owned less than 10% of the equity and voting interests issued and outstanding of Eton as of September 30, 2021.

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, potential regulatory-related restrictions, 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 near and long-term. All of these activities will require significant costs and other resources, which we may not have or be able to obtain from operations or other sources. See “Liquidity and Capital Resources” below.

Reimbursement Options

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

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 May 2020 and the following months, U.S. states and geographies began easing restrictions associated with the COVID-19 pandemic including those restrictions related to elective procedures. We have since seen sales of our products return to near historical norms and trends as restrictions associated with elective procedures and the COVID-19 pandemic have continued to ease.

However, given the unprecedented and dynamic nature of the COVID-19 pandemic virus, including any mutations/variants, we may not be able to reasonably estimate the impacts it may have on our financial condition, results of operations or cash flows in the future, especially if there are new restrictions in elective procedures in the future which would have an adverse impact, which may be material, on our future revenues, profitability and cash flows.

Recent Developments

The following describes certain developments in 2021 to date that are important to understand our financial condition and results of operations. See the notes to our condensed consolidated financial statements included in this report for additional information about each of these developments.

PPP Loan

In April 2020, we entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the “PPP Loan”) in the principal amount of \$1,967,000 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. On March 30, 2021, the Company received a notice of forgiveness of the full balance of the PPP Loan, including all accrued interest, in accordance with the terms and conditions of the CARES Act and accordingly recognized a gain on forgiveness of debt of \$1,967,000.

Eton Stock Sale

In April 2021, we closed an underwritten public offering of 1,518,000 shares of our Eton common stock at a public offering price of \$7.00 per share (the “Eton Stock Sale”). The gross proceeds to us from the Eton Stock Sale were \$10,626,000 before deducting underwriting discounts and commissions and other offering expenses payable by the Company. Following such sale, we own 1,982,000 shares of Eton common stock, which represented less than 10% of the equity interests issued and outstanding of Eton as of September 30, 2021.

As part of the Eton Stock Sale, we also agreed, for a period of 180 days, not to conduct any further sales of shares of its common stock of Eton or otherwise dispose of, directly or indirectly, any common stock of Eton (or any securities convertible into, or exercisable or exchangeable for, the common stock of Eton).

8.625% Senior Notes Due 2026

During April, May and June 2021, we closed offerings totaling \$75,000,000 aggregate principal amount of 8.625% senior notes due 2026 (the “Notes”). The Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of our other existing and future senior unsecured and unsubordinated indebtedness. The Notes are effectively subordinated in right of payment to all of our existing and future secured indebtedness and structurally subordinated to all existing and future indebtedness of the Company’s subsidiaries, including trade payables. The Notes bear interest at the rate of 8.625% per annum. Interest on the Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, commencing on July 31, 2021. The Notes will mature on April 30, 2026.

Prior to February 1, 2026, we may, at our option, redeem the Notes, in whole at any time or in part from time to time, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus a make-whole amount, if any, plus accrued and unpaid interest to, but excluding, the date of redemption. We may redeem the Notes for cash in whole or in part at any time at our option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption. On and after any redemption date, interest will cease to accrue on the redeemed Notes.

Series B Cumulative Preferred Stock - Redeemed

On May 5, 2021, we sold 440,000 shares of Series B Cumulative Preferred Stock (the “Series B Preferred Stock”) for net proceeds of \$10,670,000. On June 17, 2021, the Company redeemed all of the outstanding shares of the Series B Preferred Stock. The redemption price for the 440,000 shares of the Series B Preferred Stock outstanding was equal to \$25.00 per share, plus accrued and unpaid dividends, which in aggregate totaled \$11,127,000.

Sintetica Agreement

In July 2021, we entered into a License and Supply Agreement (the “Sintetica Agreement”) with Sintetica S.A. (“Sintetica”), pursuant to which Sintetica granted the Company the exclusive license and marketing rights to its patented ophthalmic drug candidate (“AMP-100”) in the U.S. and Canada.

Pursuant to the Sintetica Agreement, the Company will pay Sintetica a per unit transfer price to supply AMP-100, along with a per unit royalty for units sold. The Company is required to pay Sintetica up to \$18,000,000 in one-time milestone payments including a \$5,000,000 payment due within 30 days of signing the Sintetica Agreement and the balance of payments due upon achievement of certain regulatory and commercial milestones. Under the terms of the Sintetica Agreement, Sintetica will be responsible for regulatory filings for AMP-100 in the U.S.

Subject to certain limitations, the term of the Sintetica Agreement is ten years, and allows for a ten-year extension if certain sales thresholds are met.

Wakamoto Agreement

In August, 2021, we entered into a License Agreement and a Basic Sale and Purchase Agreement (together, the “Wakamoto Agreements”) with Wakamoto Pharmaceutical Co., Ltd. (“Wakamoto”), pursuant to which Wakamoto granted the Company the exclusive license and marketing rights to its ophthalmic drug candidate (“MAQ-100”) in the U.S. and Canada.

Pursuant to the Wakamoto Agreements, Wakamoto will supply MAQ-100 to us, and we will pay Wakamoto a per unit transfer price to supply MAQ-100. In addition, we are required to pay Wakamoto various one-time milestone payments totaling up to \$2,000,000 upon the achievement of certain regulatory milestones and up to \$6,200,000 upon the achievement of certain commercial milestones. Under the terms of the Wakamoto Agreements, we are responsible for regulatory filings and fees for MAQ-100 in the U.S. and Canada

Subject to certain limitations, the term of the Wakamoto Agreements is for five years from the date of the FDA’s market approval of MAQ-100 and allows for a five-year extension if certain unit sales thresholds are met.

Melt Loan

In September 2021, we entered into a loan and security agreement in the principal amount of \$13,500,000 (the “Melt Loan Agreement”), as lender, with Melt, as borrower. Amounts borrowed under the Melt Loan Agreement bear interest at twelve and one-half percent (12.50%) per annum, which can be paid in kind interest at the option of Melt until the maturity date. The Melt Loan Agreement permits Melt to pay interest only on the principal amount loaned thereunder through the term and all amounts owed will be due and payable on September 1, 2022. Melt may elect to prepay all, but not less than all, of the amounts owed prior to the maturity date at any time without penalty.

Melt has granted us a security interest in substantially all of its personal property, rights and assets, including intellectual property rights, to secure the payment of all amounts owed under the Melt Loan Agreement. The Melt Loan Agreement contains customary representations, warranties and covenants, including covenants by Melt limiting additional indebtedness, liens, mergers and acquisitions, dispositions, investments, distributions, subordinated debt, and transactions with affiliates. The Melt Loan Agreement includes customary events of default, and upon the occurrence of an event of default (subject to cure periods for certain events of default), all amounts owed by Melt thereunder may be declared immediately due and payable by the us, and the interest rate on the loan may be increased by three percent (3%) per annum.

In connection with the Melt Loan Agreement, we entered into a Right of First Refusal Agreement with Melt providing us with the right, but not the obligation, to match any offer received by Melt associated with the commercial rights to any of Melt’s drug candidates for a period of five years following the effective date of the Melt Loan Agreement.

Results of Operations

The following period-to-period comparisons of our financial results for the three and nine months ended September 30, 2021 and 2020, 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, commissions from third parties 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, 2021 and 2020:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,			\$
	2021	2020	Variance	2021	2020	Variance	
Product sales, net	\$ 17,811,000	\$ 14,385,000	\$ 3,426,000	\$ 50,056,000	\$ 34,244,000	\$ 15,812,000	
Commission revenues	900,000	-	900,000	2,212,000	-	2,212,000	
License revenues	-	14,000	(14,000)	20,000	32,000	(12,000)	
Total revenues	<u>\$ 18,711,000</u>	<u>\$ 14,399,000</u>	<u>\$ 4,312,000</u>	<u>\$ 52,288,000</u>	<u>\$ 34,276,000</u>	<u>\$ 18,012,000</u>	

The increase in revenues between periods was related to an increase in sales volumes of our ophthalmology products and commissions attributable to sales of Dexycu®.

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, 2021 and 2020:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
			\$			\$
	2021	2020	Variance	2021	2020	Variance
Cost of sales	<u>\$ 4,947,000</u>	<u>\$ 3,696,000</u>	<u>\$ 1,251,000</u>	<u>\$ 13,134,000</u>	<u>\$ 10,526,000</u>	<u>\$ 2,608,000</u>

The increase in our cost of sales between periods was largely attributable to an increase in unit volumes sold.

Gross Profit and Margin

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
			\$			\$
	2021	2020	Variance	2021	2020	Variance
Gross profit	<u>\$ 13,764,000</u>	<u>\$ 10,703,000</u>	<u>\$ 3,061,000</u>	<u>\$ 39,154,000</u>	<u>\$ 23,750,000</u>	<u>\$ 15,404,000</u>
Gross margin	<u>73.6%</u>	<u>74.7%</u>	<u>(0.8)%</u>	<u>74.9%</u>	<u>69.3%</u>	<u>5.6%</u>

The decrease in gross margin between the three months ended September 30, 2021 and 2020 is primarily attributable to a second production shift that was added in 2021 along with increased personnel within our quality department, in preparation for increased production expected during the remainder of 2021 and into 2022.

The increase in gross margin between the nine months ended September 30, 2021 and 2020 is largely attributable to increased unit volumes sold, efficiencies in our production process, including increased batch sizes, and improved utilization of capacities as a result of increased output.

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, 2021 and 2020:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
			\$			\$
	2021	2020	Variance	2021	2020	Variance
Selling, general and administrative	<u>\$ 11,356,000</u>	<u>\$ 8,436,000</u>	<u>\$ 2,920,000</u>	<u>\$ 28,643,000</u>	<u>\$ 23,806,000</u>	<u>\$ 4,837,000</u>

The increase in selling, general and administrative expenses between periods was primarily attributable to an increase in commissions and other expenses related to increased sales, and as well as an increase in our sales and marketing expenses related to in-person conferences and new employee costs to support sales growth. During the three and nine months ended September 30, 2021, the Company recorded \$1,500,000 in expenses related to a litigation settlement.

Research and Development Expenses

Our research and development (“R&D”) expenses primarily include personnel costs, including wages and stock-based compensation, expenses related to the development of intellectual property, investigator-initiated research and evaluations, formulation development, license fees, acquired in-process R&D 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, 2021 and 2020:

	For the			For the		
	Three Months Ended		\$	Nine Months Ended		\$
	September 30,			September 30,		
	2021	2020	Variance	2021	2020	Variance
Research and development	<u>\$ 6,125,000</u>	<u>\$ 670,000</u>	<u>\$ 5,455,000</u>	<u>\$ 7,142,000</u>	<u>\$ 1,822,000</u>	<u>\$ 5,320,000</u>

During the three and nine months ended September 30, 2021, research and development expenses increased between periods primarily as a result of the upfront payment of \$5,000,000 to Sintetica upon execution of the license and supply agreement for AMP-100 along with increased costs associated with the clinical program for MAQ-100.

Interest Expense, Net

Interest expense, net was \$1,685,000 and \$3,512,000 for the three and nine months ended September 30, 2021, respectively, compared to \$498,000 and \$1,563,000 for the same periods last year, respectively. The increase during the period ended September 30, 2021 compared to the same period in 2020 was primarily due to an increase in the outstanding principal amount of our debt obligations.

Investment Loss from Melt

During the three and nine months ended September 30, 2021, we recorded a loss of \$706,000 and \$1,653,000, respectively, related to our share of losses in Melt. 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.

Investment Loss from Surface

During the three and nine months ended September 30, 2021, we recorded a loss of \$0 and \$1,314,000, respectively, for our share of losses based on our ownership of Surface. 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.

Investment (Loss) Gain from Eton

We recorded a loss of \$2,220,000 and \$8,639,000 related to the change in fair market value of Eton’s common stock and the sale of a portion of our Eton stock during the three and nine months ended September 30, 2021, respectively. 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 during the three and nine months ended September 30, 2020, respectively.

Loss From Early Extinguishment of Loan

During the nine months ended September 30, 2021, we recorded a loss from the early extinguishment of loan of \$756,000 related to the early payoff of the SWK Loan.

Gain on Forgiveness of PPP Loan

During the nine months ended September 30, 2021, we recorded gain on forgiveness of PPP loan of \$1,967,000 related to the forgiveness of our PPP Loan.

Net (Loss) Income

The following table presents our net (loss) income and per share net (loss) income for the three and nine months ended September 30, 2021 and 2020:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator – net (loss) income attributable to Harrow Health, Inc. common stockholders	\$ (8,328,000)	\$ 8,638,000	\$ (11,061,000)	\$ (4,506,000)
Net (loss) income per share, basic	\$ (0.31)	\$ 0.33	\$ (0.42)	\$ (0.17)
Net (loss) income per share, diluted	\$ (0.31)	\$ 0.32	\$ (0.42)	\$ (0.17)

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 business ImprimisRx; and (ii) the start-up operations associated with our pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for the segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. We do not evaluate the following items at the segment level:

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

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

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

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

See Note 16 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, 2021 was \$57,856,000, compared to \$4,301,000 at December 31, 2020.

As of the date of this Quarterly Report, we believe that cash and cash equivalents of \$57,656,000 and restricted cash of \$200,000, totaling approximately \$57,856,000 at September 30, 2021, will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. In addition, we may consider the sale of certain assets including, but not limited to, part of, or all of, our ownership interest in Eton, Surface, Melt, and/or any of our consolidated subsidiaries. However, we may pursue acquisitions of pharmacies, revenue generating products, drug candidates or other strategic transactions that involve large expenditures or we may experience growth more quickly or on a larger scale than we expect, any of which could result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing 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 drug candidates, compounded formulations and technologies, integrating and developing our operations, pursuing potential future strategic transactions as opportunities arise, including potential acquisitions of additional pharmacy, outsourcing facilities, drug company and manufacturers, drug products, drug candidates, 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,	
	2021	2020
Net cash provided by (used in):		
Operating activities	\$ 6,572,000	\$ (534,000)
Investing activities	(4,489,000)	(891,000)
Financing activities	51,472,000	2,203,000
Net change in cash and cash equivalents	53,555,000	778,000
Cash, cash equivalents and restricted cash at beginning of the period	4,301,000	4,949,000
Cash, cash equivalents and restricted cash at end of the period	<u>\$ 57,856,000</u>	<u>\$ 5,727,000</u>

Operating Activities

Net cash provided by operating activities during the nine months ended September 30, 2021 was \$6,572,000 compared to net cash used in operating activities of \$534,000 during the same period in the prior year. The increase in net cash provided by operating activities during the periods was mainly attributed to the increase in revenues.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2021 was \$4,489,000 compared to net cash used in investing activities of \$891,000, during the same period in the prior year. Cash used in investing activities in 2021 was primarily associated with cash payments made in connection with the Melt note receivable offset by cash received through the sale of a portion of our Eton Common Stock. Cash used in investing activities during the 2020 period was primarily associated with equipment and software purchases and upgrades along with investments in our intellectual property portfolio.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2021 and 2020 was \$51,472,000 and \$2,203,000, respectively. Cash provided by financing activities during the nine months ended September 30, 2021 was primarily related to proceeds received from the sale of Notes, net of the payment of all outstanding obligations to the Company's previous senior lender, SWK Funding, LLC and its partners.

Sources of Capital

Our principal sources of cash consist of cash provided by operating activities from our ImprimisRx business, and recently, proceeds from the sale of the Notes and sale of Eton Common Stock. We may also sell some or all of our ownership interests in Surface, Melt or our other subsidiaries, along with the some or all of the remaining portion of our Eton common stock.

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

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

Recently Issued and Adopted Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Under the supervision and with the participation of our principal executive officer and principal financial officer, our management conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act, as they existed on September 30, 2021. 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, 2021, 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, 2021, 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 15 to our condensed consolidated financial statements included in this 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 when evaluating our business as well as the risk factors and the other information in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021 and June 30, 2021 and in our Annual Report on Form 10-K for the year ended December 31, 2020, including our audited financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” 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.

Risks Related to the Senior Notes

We have incurred significant indebtedness, which will require substantial cash to service and which subjects us to certain financial requirements and business restrictions.

In April, May and June 2021, we issued \$75,000,000 aggregate principal amount of 8.625% senior notes due 2026. We may incur additional indebtedness in the future. Our ability to make scheduled payments on our indebtedness depends on our future performance and ability to raise additional capital, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional capital through equity sales or incurrence of additional debt on terms that may be onerous or highly dilutive to our stockholders. Our ability to engage in any of these activities would depend on the capital markets and our financial condition at such time, and we may not be able to do so when needed, on desirable terms or at all, which could result in a default on our debt obligations. Additionally, our debt instruments contain or, from time to time, may contain various restrictive covenants, including, among others, our obligation to deliver certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without prior consent, to dispose of certain of our assets, incur certain additional indebtedness, enter into certain merger, acquisition or change of control transactions, pay certain dividends or distributions on or repurchase any of our capital stock or incur any lien or other encumbrance on our assets, subject to certain permitted exceptions. Any failure by us to comply with any of these covenants, subject to certain cure periods, or to make all payments under the debt instruments when due, would cause us to be in default under the applicable debt instrument. In the event of any such default, lenders may be able to foreclose on our assets that secure the debt or declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially causing all of our available cash to be used to pay our indebtedness or forcing us into bankruptcy or liquidation if we do not then have sufficient cash available. Any such event or occurrence could severely and negatively impact our operations and prospects.

We may need additional capital in order to continue operating our business, and such additional funds may not be available when needed, on acceptable terms, or at all.

We only recently started generating cash from operations, but we do not currently earn sufficient revenues to support our operations. We may need significant additional capital to execute our business plan and fund our proposed business operations. Additionally, our plans may change or the estimates of our operating expenses and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies or other strategic transactions that involve large expenditures, or we may experience growth more quickly or on a larger scale than we expect, any of which may 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 have raised over \$85,000,000 in funds through equity and debt financings in April, May and June 2021. We may seek to obtain additional capital through equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or other financing transactions. If we issue additional equity or debt securities to raise 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 and licensing arrangements or sales of assets, we may have to relinquish potentially valuable rights to our drug candidates or proprietary technologies, 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 those loans would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as options, convertible notes and warrants, which would adversely impact our financial results.

The Notes are unsecured and therefore are effectively subordinated to any secured indebtedness that we currently have or that we may incur in the future.

The Notes are not secured by any of our assets or any of the assets of our subsidiaries. As a result, the Notes are effectively subordinated to any secured indebtedness that we or our subsidiaries have currently outstanding or may incur in the future (or any indebtedness that is initially unsecured to which we subsequently grant security) to the extent of the value of the assets securing such indebtedness. The indenture governing the Notes does not prohibit us or our subsidiaries from incurring additional secured (or unsecured) indebtedness in the future. In any liquidation, dissolution, bankruptcy or other similar proceeding, the holders of any of our existing or future secured indebtedness and the secured indebtedness of our subsidiaries may assert rights against the assets pledged to secure that indebtedness and may consequently receive payment from these assets before they may be used to pay other creditors, including the holders of the Notes.

The indenture under which the Notes were issued contains limited protection for holders of the Notes.

The indenture under which the Notes were issued offers limited protection to holders of the Notes. The terms of the indenture and the Notes do not restrict our or any of our subsidiaries' ability to engage in, or otherwise be a party to, a variety of corporate transactions, circumstances or events that could have an adverse impact on the holders of the Notes. In particular, the terms of the indenture and the Notes do not place any restrictions on our or our subsidiaries' ability to:

- issue debt securities or otherwise incur additional indebtedness or other obligations, including (1) any indebtedness or other obligations that would be equal in right of payment to the Notes, (2) any indebtedness or other obligations that would be secured and therefore rank effectively senior in right of payment to the Notes to the extent of the values of the assets securing such debt, (3) indebtedness of ours that is guaranteed by one or more of our subsidiaries and which therefore is structurally senior to the Notes and (4) securities, indebtedness or obligations issued or incurred by our subsidiaries that would be senior to our equity interests in our subsidiaries and therefore rank structurally senior to the Notes with respect to the assets of our subsidiaries;
- pay dividends on, or purchase or redeem or make any payments in respect of, capital stock or other securities subordinated in right of payment to the Notes;
- sell assets (other than certain limited restrictions on our ability to consolidate, merge or sell all or substantially all of our assets);
- enter into transactions with affiliates;
- create liens (including liens on the shares of our subsidiaries) or enter into sale and leaseback transactions;
- make investments; or
- create restrictions on the payment of dividends or other amounts to us from our subsidiaries.

In addition, the indenture does not include any protection against certain events, such as a change of control, leveraged recapitalization, “going private” transaction (which may result in a significant increase of our indebtedness), restructuring or similar transactions. Furthermore, the terms of the indenture and the Notes do not protect holders of the Notes in the event that we experience changes (including significant adverse changes) in our financial condition, results of operations or credit ratings, as they do not require that we or our subsidiaries adhere to any financial tests or ratios or specified levels of net worth, revenues, income, cash flow, or liquidity. Also, an event of default or acceleration under our other indebtedness would not necessarily result in an event of default under the Notes.

Our ability to recapitalize, incur additional debt and take a number of other actions that are not limited by the terms of the Notes may have important consequences for the holders of the Notes, including making it more difficult for us to satisfy our obligations with respect to the Notes or negatively affecting the trading value of the Notes.

Other debt we issue or incur in the future could contain more protections for its holders than the indenture and the Notes, including additional covenants and events of default. The issuance or incurrence of any such debt with incremental protections could affect the market for and trading levels and prices of the Notes.

An increase in market interest rates could result in a decrease in the value of the Notes.

In general, as market interest rates rise, notes bearing interest at a fixed rate decline in value. Consequently, if the market interest rates increase, the market value of the Notes may decline. We cannot predict the future level of market interest rates.

An active trading market for the Notes may not develop, which could adversely affect the market price of the Notes or limit a holder’s ability to sell them.

The Notes are quoted on Nasdaq under the symbol “HROWL.” We cannot provide any assurances that an active trading market will develop for the Notes or that a holder will be able to sell the Notes. If the Notes are traded, they may trade at a discount from their initial offering price depending on prevailing interest rates, the market for similar securities, our credit ratings, general economic conditions, our financial condition, performance and prospects and other factors. The underwriters of the Notes may make a market in the Notes, but they are not obligated to do so. The underwriters may discontinue any market-making in the Notes at any time at their sole discretion. Accordingly, we cannot assure a holder that a liquid trading market will develop for the Notes, that a holder will be able to sell the Notes at a particular time or that the price received will be favorable. To the extent an active trading market does not develop, the liquidity and trading price for the Notes may be harmed. Accordingly, a holder may be required to bear the financial risk of an investment in the Notes for an indefinite period of time.

We may issue additional notes.

Under the terms of the indenture governing the Notes, we may from time to time without notice to, or the consent of, the holders of the Notes, create and issue additional notes which will be equal in rank to the Notes.

The rating for the Notes could at any time be revised downward or withdrawn entirely at the discretion of the issuing rating agency.

We have obtained a rating for the Notes. Ratings only reflect the views of the issuing rating agency or agencies and such ratings could at any time be revised downward or withdrawn entirely at the discretion of the issuing rating agency. A rating is not a recommendation to purchase, sell or hold the Notes. Ratings do not reflect market prices or suitability of a security for a particular investor and the rating of the Notes may not reflect all risks related to us and our business, or the structure or market value of the Notes. We may elect to issue other securities for which we may seek to obtain a rating in the future. If we issue other securities with ratings lower than market expectations or that are subsequently lowered or withdrawn, the market for or the market value of the Notes could be adversely affected.

We could enter into various transactions that could increase the amount of our outstanding debt, or adversely affect our capital structure or credit rating.

Subject to certain limited exceptions, the terms of the Notes do not prevent us from entering into a variety of acquisition, divestiture, refinancing, recapitalization or other highly leveraged transactions. As a result, we could enter into any such transaction even though the transaction could increase the total amount of our outstanding indebtedness, adversely affect our capital structure or credit rating or otherwise adversely affect the holders of the Notes.

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

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 Court against Kim Kelly, ND, MPH asserting claims related to the death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming us as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against the Company and various entities affiliated with Spectrum Laboratory Products, Inc., Spectrum Chemical Manufacturing Corp. and Spectrum Pharmacy Products, Inc. (collectively "Spectrum"). The cross-complaint sought indemnity and contribution from us and Spectrum. In November 2021, the lawsuit involving us was resolved. There was no impact to our consolidated financial position and results of operations as a result of the resolution of the case.

Item 6. Exhibits

Exhibit Number	Description
10.1#	License and Supply Agreement, dated as of July 25, 2021, by and between the Company and Sintetica, S.A. (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company filed with the SEC on August 10, 2021).
10.2	Loan and Security Agreement, dated September 1, 2021, by and between the Company and Melt Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the SEC on September 2, 2021).
10.3**	Basic Sale and Purchase Agreement, dated as of August 18, 2021, by and between the Company and Wakamoto Pharmaceutical Co., Ltd.
10.4**	License Agreement, dated as of August 18, 2021, by and between the Company and Wakamoto Pharmaceutical Co., Ltd.
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, 2021, 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, 2021

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 Harrow Health, Inc. and Wakamoto Pharmaceutical Co., LTD. if publicly disclosed.

BASIC SALE AND PURCHASE AGREEMENT

This BASIC SALE AND PURCHASE AGREEMENT (hereinafter referred to as this “Agreement”) made and entered into this 18th day of August, 2021 (hereinafter referred to as the “Effective Date”), by and between WAKAMOTO PHARMACEUTICAL CO., LTD., a corporation duly incorporated and existing under the laws of Japan, having its principal place of business at 2-2, Nihonbashi Honcho 2-chome, Chuo-ku, Tokyo, 103-8330 Japan (hereinafter referred to as “Wakamoto”) and Harrow Health, Inc., a corporation organized and existing under the laws of State of Delaware, having its principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 USA (hereinafter referred to as “Harrow”),

WITNESSETH:

WHEREAS, Wakamoto is a developer, manufacturer, and supplier of products relating to pharmaceuticals and Harrow is a distributor of finished pharmaceutical products;

WHEREAS, Wakamoto and Harrow have been respectively interested in sale by Wakamoto and purchase by Harrow of the certain products and have explored a business opportunity in the United States of America and Canada including their territories and possessions (hereinafter referred to as “Territory”), by using their respective capabilities;

WHEREAS, Wakamoto and Harrow are concurrently executing a License Agreement as of the Effective Date regarding the Development and Commercialization of the Product, as those terms are defined in the License Agreement (the “**License Agreement**”); and

WHEREAS, Wakamoto and Harrow have basically reached common understanding that it would be beneficial for each party to promote the certain sale and purchase;

NOW, THEREFORE, it is hereby agreed upon by the parties hereto as follows:

1 Product and Transactions

In accordance with the provisions of this Agreement, Wakamoto shall continuously sell the products separately agreed upon by the parties following the basic conditions as set forth in Annex 1 attached hereto (hereinafter referred to as the “Product”) to Harrow, and Harrow shall purchase the Product from Wakamoto at the prices as set forth in Annex 1. Both parties agree that Wakamoto shall exclusively supply the Product to Harrow in the Territory and Harrow shall purchase all of its requirements of the Product in the Territory exclusively from Wakamoto. Harrow’s purchases of each order of Product shall be made through purchase orders/individual agreements (hereinafter referred to as the “Individual Agreement”).

2 Order Schedule and Individual Agreement

- 2.1 Harrow shall inform Wakamoto of the scheduled order of the Product for the next one (1) year until the end of [***]. The quantity of the scheduled order shall have no binding force on Wakamoto and Harrow, but the Parties shall make their best effort to observe such schedule, and if there is wide ranging change in the schedule, Harrow shall notify thereof to Wakamoto without delay.
- 2.2 The Individual Agreement shall be established through the offer by Harrow submitting a written purchase order, which specifies the name, the quantity, the unit price, the delivery time, the delivery place, the trade conditions, the package for delivery and otherwise of the Product and the acceptance thereof by Wakamoto submitting the written acceptance of the purchase order to Harrow. Harrow shall submit the Individual Agreement to Wakamoto not less than [***] before the desired delivery time, and upon submitting the written acceptance by Wakamoto, each Individual Agreement shall be properly established. In the event the Wakamoto can offer Harrow a shortened lead time for Individual Agreements, Wakamoto shall advise Harrow of such shortened lead time.
- 2.3 In the event that Wakamoto is unable to meet the scheduled order from Harrow as set forth in Article 2.1, Wakamoto and Harrow shall meet and confer in good faith discussions to determine how best to satisfy Harrow's demand, including considering adding or changing the site for manufacturing of Product for Individual Agreements.
- 2.4 In the event that Wakamoto is unable to deliver Product on or before the scheduled delivery date in an Individual Agreement, Wakamoto shall notify Harrow of that fact without delay and consult about the countermeasure. The Parties shall work together to implement a satisfactory countermeasure, but if the Parties jointly agree, orders for Individual Agreements can be canceled.

3 Delivery

- 3.1 The delivery time shall mean the date that Wakamoto shall deliver the Product stipulated in the Individual Agreement to the place designated by Harrow and shall be decided between the parties hereto in each Individual Agreement. Wakamoto and Harrow, however, may designate the delivery time in the certain term or the certain deadline in the Individual Agreement.
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3.2 Unless otherwise agreed upon by the parties in the Individual Agreement, Wakamoto shall deliver the Product upon CIF Newark International Airport (EWR), the United States of America basis in accordance with the delivery time and the delivery place specified in the Individual Agreement. Upon the proper delivery of the Product, the written receipt of the Product shall be submitted to Wakamoto.

3.3 Wakamoto and Harrow shall discuss and agree upon when they intend to change the delivery time.

3.4 Customs and Other Duties. All duties and charges, including government levy and customs duties, in the country in which Wakamoto's manufacturing facility is located, including any duties, taxes, VATs or similar charges arising with respect to the manufacture, sale, exportation and shipment of the Product by Wakamoto to Harrow, shall be borne and paid by Wakamoto.

4 Acceptance of Product

4.1 Harrow shall conduct the inspections of the external appearance and the quantity within [***] of Harrow after the delivery of the Product, and the time point of the pass of such inspections of the external appearance and the quantity shall be the acceptance of such Product by Harrow, provided, however, that Harrow's acceptance of the Product shall not relieve Wakamoto from any liability or obligation with respect to the Product hereunder.

4.2 If the Product does not pass the inspections of the external appearance and the quantity set forth in Article 4.1 above, Harrow shall notify Wakamoto of such effect without delay, and Wakamoto shall, under instructions by Harrow, conduct the delivery of the replacement of the Product, the decrease of the price amount in accordance with the short of the quantity or otherwise.

5 Transfer of Ownership

The ownership of the Product shall be transferred from Wakamoto to Harrow as soon as the Product has set down inside the ship/airplane, even in the case where the payment of the price amount has not been made yet.

6 Quality Assurance

Wakamoto represents and warrants that the quality of the Product to be sold to Harrow hereunder meets the items and the standards with respect to the quality separately agreed upon by the parties hereto, which items and standards shall be in compliance with cGMPs and all Applicable Laws. The separate quality agreement shall be entered into at least nine (9) months prior to delivery of the launch quantities of the Product.

7 Quality Inspection

- 7.1 Harrow shall conduct the quality inspection after the acceptance of the Product without delay, and notify Wakamoto of the result thereof.
- 7.2 The quality inspection set forth in Article 7.1 above shall be conducted in accordance with the ways and standards of the inspection in matters with respect to the quality separately agreed upon by the parties hereto.

8 Measures upon Rejection

As a result of the quality inspection set forth in Article 7 above, if the rejected Product occurs by incongruence, Harrow shall notify Wakamoto of such effect within [***] after receiving the Product from Wakamoto in the case of apparent defects, or [***] from discovery by Harrow in the case of latent defects, and if that fact is also confirmed by Wakamoto, Wakamoto shall refund or subtract the price amount equivalent to that of the rejected Product from Harrow's amount of payment. However, if Wakamoto and Harrow have inconsistencies to the incongruence of the Product, Wakamoto and Harrow agree to request the independent third party of recognized repute enough to evaluate the incongruence of the Product to take final confirmation with prior agreement between Wakamoto and Harrow, and the parties shall not have any objections to the result. The fees and expenses of the third party making the determination shall be paid by Harrow if the Product is found to be in compliance with the Specifications and cGMPs; otherwise, such fees and expenses shall be paid by Wakamoto.

9 Warranty/Indemnification/Insurance

- 9.1 Wakamoto represents and warrants that it has the full authority to perform its obligations provided hereunder, including but not limited to rights and licenses to sell the Product.
- 9.2 Wakamoto represents and warrants that any item in the Product in every respect is free from any defect and error for a period of [***] from the acceptance thereof in accordance with Article 4.1 above. All Product delivered to Harrow will meet the Specifications, and shall be manufactured and labeled in compliance with cGMPs, all Applicable Laws and the Quality Agreement. All Product, when delivered to Harrow, shall not be adulterated or misbranded and will, at the time of such delivery, be free and clear of all liens, security interests and other encumbrances. Wakamoto's method of manufacturing the Product shall not violate any third party intellectual property rights. If any defect or error is discovered in any item in the Product, Wakamoto shall, immediately, at Wakamoto's sole cost and expense, correct such defect and error or replace such Product under instructions by Harrow.
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- 9.3 Wakamoto Indemnification. Wakamoto shall indemnify and hold Harrow, and its Affiliates, and their respective officers, directors, shareholders, employees, agents and representatives (collectively “Harrow Indemnitees”) harmless from any damage, expense, loss, or liability, including reasonable attorney’s fees, arising out of or resulting from any third party claims against Harrow, to the extent caused by (i) a violation of any of Wakamoto’s warranties (ii) the negligence or willful misconduct of Wakamoto, or (iii) Wakamoto’s breach of this Agreement, including failure to perform any act required by or in compliance with Wakamoto’s obligations under this Agreement or another breach of this Agreement; provided, however, that Wakamoto shall not have any obligation to indemnify Harrow to the extent a claim results from the negligence or willful misconduct of Harrow or Harrow’s breach of this Agreement. Harrow shall give Wakamoto notice of any claim for which Harrow may be entitled to indemnification and shall cooperate with Wakamoto in the defense of such claims. Notwithstanding the foregoing, at its election, and at its own expense, Wakamoto (or its insurers) may assume direction and control of the defense of any such claim.
- 9.4 Harrow Indemnification. Harrow shall indemnify and hold Wakamoto, and its Affiliates, and their respective officers, directors, shareholders, employees, agents and representatives (collectively “Wakamoto Indemnitees”) harmless from any damage, expense, loss, or liability, including reasonable attorney’s fees, arising out of or resulting from any third party claims made or threatened against Wakamoto to the extent caused by (i) any failure of Harrow to comply with any Applicable Law regarding the possession, distribution, labeling, or sale of the Product, (ii) the negligence or willful misconduct of Harrow, and (iii) violation of any of Harrow’s warranties, provided, however, that Harrow shall not have any obligation to indemnify Wakamoto to the extent a claim is caused by the negligence or willful misconduct of Wakamoto or Wakamoto’s breach of this Agreement. Wakamoto shall give Harrow notice of any claim for which Wakamoto may be entitled to indemnification and shall cooperate with Harrow in the defense of such claims.
- 9.5 Insurance. Each Party shall maintain adequate insurance to protect itself from and against any claims or liabilities that may arise directly or indirectly as a result of its performance under this Agreement. A Party shall notify the other Party at least [***] prior to any cancellation of an insurance policy subject to this Section 9.5.
- 9.6 The provisions under this Article 9 shall also apply for the License Agreement.
- 10 Payment of Price
After receiving the air waybill for the amount of Product shipped (AWB), Harrow shall pay the total amount for such shipped Product to Wakamoto by telegraphic/wire transfer to Wakamoto’s bank account within [***] from AWB date, provided, however, that the parties may agree upon different payment conditions thereafter with mutual written agreement.
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11 Confidentiality.

- 11.1 No party hereto may disclose the fact that Wakamoto and Harrow have executed and delivered this Agreement and any contents hereof to any third party without prior written consent of the other party, unless the fact or the content in question meets any one of (a) through (f) set forth in Article 11.3 below.
- 11.2 Each party hereto agrees, during the effective term hereof and for five (5) years after expiration or termination hereof, not to disclose the confidential information of the other party, which means all of proprietary or non-public information, including but not limited to any and all verbal, written, graphic, or electronically transmitted and/or machine-reproduced trade secrets, electronic files, software, hardware, patents and patent applications, including but not limited to drawings, claims, and amendments, inventions, know-how, samples, prototypes, models, parts, technical drawings, specifications, designs, depictions, ideas, works of authorship, improvements, developments, plans for research and development, present or future products, testing information, business and business practices, customers, suppliers, prices, works in progress, marketing plans or strategies, finances, and sales, disclosed, received, or known, whether directly or indirectly, from the other party hereto (hereinafter referred to as the "Confidential Information") to any third party, to keep the Confidential Information in strict confidence and secret with a duty of due care of a prudent manager, and not to use the Confidential Information for any other purpose than the performance of this Agreement without prior written consent of the other party.
- 11.3 Notwithstanding the provision of Article 11.2 above, any of the following information shall not be included in nor considered as the Confidential Information.
- (a) Information, which is already publicly available at the time of disclosure, receipt, or knowing;
 - (b) Information, which becomes publicly available after disclosure, receipt, or knowing without any default of the receiving or knowing party;
 - (c) Information, which is already known to the disclosed, receiving or knowing party at the time of disclosure, receipt, or knowing;
 - (d) Information, which is independently learned or developed by the disclosed, receiving or knowing party without any use of or access to the Confidential Information;
 - (e) Information, which is disclosed, received or known from a third party who is not in breach of an obligation of confidentiality or secrecy; or
 - (f) Information, which is disclosed to the judicial or governmental authorities or other third parties under and within requirement by a valid subpoena, warrant, order or similar thereto, which has proper legal or equitable compelling force.
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- 11.4 Any Confidential Information to be disclosed hereunder in tangible form shall be clearly marked "Confidential," "Proprietary," "Secret," or other description, which reasonably represents the confidential, proprietary, or secret nature thereof and if the Confidential Information is to be disclosed orally or visually, the disclosing party shall designate it as Confidential Information upon such oral or visual disclosure and provide the other party a written notification, which specifies and summarizes such orally or visually disclosed Confidential Information, within thirty (30) days after such oral or visual disclosure. Notwithstanding the above, the failure to mark any such information shall not relieve the receiving party of its obligations under this Article if the information would readily be understood to be proprietary information of the disclosing party.
- 11.5 If either party hereto wishes to make any copy or extract of the Confidential Information, such party hereto shall obtain prior written consent of the other party hereto and maintain such copy or extract in strict confidence and secret as well as set forth herein.
- 11.6 If either party breaches any of its obligations with respect to the Confidential Information hereunder, the other party shall be entitled to seek any specific performance and/or injunctive relief to protect its interests therein.
- 11.7 Upon any written request by the disclosing party, or if no request is made, upon expiration or termination of this Agreement, the other party shall promptly return to the disclosing party any Confidential Information and all copies, extracts, and other materials, which contain the Confidential Information, including but not limited to drawings, documents, and electromagnetic records, or, alternatively, if instructed by the disclosing party, shall destroy the Confidential Information and such copies, extracts, and materials. Following the return or destruction of any Confidential Information and such copies, extracts, and materials, the other party shall provide the disclosing party hereto with a certificate confirming that any Confidential Information, including all copies, extracts, and other materials, which contain the Confidential Information, has been either returned or destroyed.
- 11.8 The provisions under this Article 11 shall also apply for the License Agreement.

12 Report

Wakamoto may anytime require the report by Harrow with respect to the performance and the compliance of this Agreement and/or the Individual Agreement and Harrow shall promptly respond to such requirement.

13 Audit

A Party may upon prior written notice to the other Party not more than once per year, except for cause where quality issues are identified, enter the other Party's facilities for the purpose of the audit of the situation of the performance and the compliance by such other Party of this Agreement and/or the Individual Agreement, and such other Party shall cooperate thereto.

14 LIMITATION OF LIABILITY

EXCEPT IN THE CASE OF WILLFUL MISCONDUCT, FRAUD OR INDEMNITY OBLIGATIONS, IN NO EVENT SHALL WAKAMOTO AND ITS AFFILIATES, INCLUDING THEIR RESPECTIVE SHAREHOLDERS, DIRECTORS, OFFICERS, EMPLOYEES, AND AGENTS, BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGE(S), OR SIMILAR THERETO, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, REGARDLESS OF THE BASIS OF THE CLAIM, ARISING OUT OF OR RELATING TO OR IN CONNECTION WITH THIS AGREEMENT, OR THE BREACH THEREOF, EVEN IF WAKAMOTO OR ITS AFFILIATES, INCLUDING THEIR RESPECTIVE SHAREHOLDERS, DIRECTORS, OFFICERS, EMPLOYEES, AND AGENTS, HAS BEEN ADVISED, KNEW OR SHOULD HAVE KNOWN THE POSSIBILITY OF SUCH DAMAGE(S). EXCEPT IN THE CASE OF WILLFUL MISCONDUCT, FRAUD OR INDEMNITY OBLIGATIONS, IN CASE OF ANY CLAIM BY HARROW AGAINST WAKAMOTO AND/OR ITS AFFILIATE, INCLUDING THEIR RESPECTIVE SHAREHOLDERS, DIRECTORS, OFFICERS, EMPLOYEES, AND AGENTS, ARISING OUT OF OR RELATING TO OR IN CONNECTION WITH THIS AGREEMENT, OR THE BREACH THEREOF, WAKAMOTO'S AND ITS AFFILIATES' TOTAL LIABILITY SHALL BE LIMITED TO THE PRICE AMOUNT WHICH HAS BEEN ALREADY RECEIVED BY WAKAMOTO FROM HARROW UNDER THIS AGREEMENT DURING A YEAR IN WHICH THE CAUSE OF SUCH DAMAGE(S) OCCURS. THE PARTIES HERETO ACKNOWLEDGE AND AGREE THAT THE LIMITATION OF LIABILITY SET FORTH IN THIS ARTICLE 14 IS A REASONABLE ALLOCATION OF RISK BETWEEN THE PARTIES HERETO AND REFLECTS THE RESPECTIVE REMUNERATION AND POTENTIAL LIABILITIES WHICH THE PARTIES HERETO REASONABLY EXPECT TO RECEIVE AND/OR INCUR. THIS PROVISION SHALL ALSO APPLY FOR THE LICENSE AGREEMENT.

15 Effective Term

This Agreement shall become effective as of the Effective Date first above written and be in full force until the end of the fifth (5th) year from the date of first approval of the Product in the Territory, with Harrow allowed an option to extend for additional five year renewal terms once [***] units of the Licensed Product are sold by Harrow annually, provided, however, that this Agreement is not terminated earlier in accordance with Article 16. The provisions under this Article 15 and those of Articles 16 and 17 shall also apply for the License Agreement.

16 Early Termination

16.1 Either party hereto may terminate a part of or a whole of this Agreement and/or the Individual Agreement upon written notice in the event the other party fails to comply with any one of the terms and conditions of this Agreement and/or the Individual Agreement and fails to cure such non-compliance within thirty (30) days of receiving written notice thereof.

16.2 Either party hereto may immediately terminate a part of or a whole of this Agreement and/or the Individual Agreements without giving a notice, if the other party hereto:

- (a) becomes insolvent, files an application for bankruptcy, enters into corporate reorganization proceedings or civil rehabilitation proceedings, or any other similar procedures for remedy under the applicable laws;
- (b) is judicially or governmentally attached or forfeited, whether wholly or partly, its business or assets;
- (c) resolves its dissolution or liquidation;
- (d) is transferred, sold, merged, acquired, or disposed, whether wholly or partly, in its business or assets relating hereto;
- (e) is changed in its control, controllable ownership, or principal shareholder; or
- (f) materially breaches any one of the terms and conditions of this Agreement and/or the Individual Agreement.

If either party meets any one of items (a) through (e) above, such party shall immediately notify the other party of such effect in writing.

16.3 Each Party acknowledges and agrees that, in the case that Harrow fails to launch the Product within four (4) years from the Effective Date, Wakamoto shall have a right to terminate this Agreement, in whole or in part.

16.4 Furthermore, the terminated party in accordance with the provisions of Article 16.1, 16.2, or 16.3 above shall forfeit the benefit of time and shall immediately make payment of any and all debt hereunder in cash to the terminating party.

17 After Expiration or Termination

17.1 After expiration or termination of this Agreement, the parties hereto shall be released from any obligations or responsibilities hereunder, except for those set forth in the provisions of this Agreement, which survive any expiration or termination as set forth in Article 17.2 below.

17.2 The provisions of Articles 9, 11, 14, 16.3 and 17 through 31, and other provisions which by their nature or content shall survive any expiration or termination of this Agreement. For the avoidance of doubt, any Individual Agreement for the purchase of Product materialized before such expiration or termination of this agreement shall remain in effect and Harrow shall have the obligation to make payment of the price of Product under such Individual Agreement provided that Wakamoto delivers such Product to Harrow as is set forth in the Individual Agreement.

18 Elimination of Anti-social Forces

18.1 Wakamoto and Harrow each represent and warrant to the other party the following matters upon the Effective Date and for the future:

- (a) Itself and its executives or persons, which have substantial influence on the management, including but not limited to employees in important positions (hereinafter collectively referred to as the "Executives") are not organized crime groups, members of an organized crime group, persons for whom five (5) years have not yet passed since leaving an organized crime group, associate members of an organized crime group, corporations related to an organized crime group, corporate racketeers, thug groups pretending to be social activists, special intellectual violent organizations, or others equivalent thereto (hereinafter collectively referred to as the "ASFs");
- (b) The ASFs do not control the management;
- (c) The ASFs do not substantially relate to the management;
- (d) Itself and the Executives do not cooperate in or have relation to maintenance or operation of the ASFs, by, including without limitation, offering funds or giving special treatment to the ASFs; and
- (e) In addition to the above, itself and the Executives have no relation which should be socially reprehensible to the ASFs.

18.2 Wakamoto and Harrow shall not, whether by itself or through a third party, conduct any act which meets any one of the following against the other party, its Executives, employees, shareholders, affiliates and subsidiaries, business connections or others equivalent thereto:

- (a) Demand with violence;
- (b) Unjustly demand beyond legal liability;
- (c) Threaten with speech and behavior or use violence with respect to transactions;
- (d) Damage honor or credit of the other party through spreading rumors, or use fraudulent means or force, or interrupt business of the other party; or
- (e) In addition to the above, act that is equivalent to (a) through (d) above.

18.3 If any matter which breaches any one of the items in Article 18.1 or 18.2 above is found, Wakamoto and Harrow shall immediately notify the other party of such fact.

18.4 Wakamoto and Harrow may, if the other party breaches any one of provisions of Articles 18.1 through 18.3 above, cancel any and all agreements related to the transactions, immediately, without demand and by written notice, and may claim damages arising out of or in connection with such cancellation against the other party.

18.5 In the case where Wakamoto or Harrow cancels the agreement pursuant to Article 18.4 above, the canceling party shall have neither liability nor responsibility for damages, even if the other party incurs the damage or loss by such cancellation.

19 Governing Law and Trade Conditions

19.1 This Agreement has been executed and delivered at Delaware, The United States of America and shall be governed by and construed in accordance with the laws of Delaware, without application of conflict of law principles thereof. The application of the U.N. Convention on Contracts for the International Sale of Goods (1980) is excluded.

19.2 The terms and conditions for delivery and trade arising out of or relating to or in connection with this Agreement, if any, shall be construed in accordance with the Incoterms 2020 (International Chamber of Commerce Publication Number 715, ICC Rules for the Use of Domestic and International Trade Terms).

19.3 The provisions of this Article 19, and Articles 20-26 and 28-31 shall also apply for the License Agreement.

20 Arbitration

All disputes arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The place of arbitration shall be Delaware if the arbitration is requested by Wakamoto or Tokyo, Japan if the arbitration is requested by Harrow. The language of arbitration shall be the English language. The arbitral award is final and shall be binding on both parties, but if the arbitral award is dissatisfied, each party may apply to the court having jurisdiction over the enforcement of the arbitral award.

21 Notice

21.1 All notices and other communications between the parties under or relating to or in connection with this Agreement shall be delivered in writing to the respective parties at the address set forth in Article 21.3 below. Such notices and other communications shall be deemed effective upon the earliest to occur of: (a) actual delivery; (b) seven (7) business days after mailing via registered airmail, addressed and postage prepaid; or (c) actual receipt by the receiving party via facsimile or electronic mail.

21.2 The Parties agree that (a) the Product shall be initially manufactured at Wakamoto's third party manufacturer in [***] (which currently supplies the Japanese market), and (b) [***].

21.3 All notices and other communications between the parties under or relating to or in connection with this Agreement shall be addressed to the following or as otherwise directed in writing by either party to the other party:

To Harrow:

Harrow Health, Inc.
102 Woodmont Blvd. Suite 610
Nashville, TN 37205
United States of America
Attention: Andrew Boll
Facsimile:
E-mail:

To Wakamoto:

WAKAMOTO PHARMACEUTICAL CO., LTD.
2-2, Nihonbashi Honcho 2-chome
Chuo-ku, Tokyo, 103-8330
Japan
Attention: Atsushi Saito (Mr.)
Facsimile:
E-mail:

21.4 No provision herein, however, may be construed nor interpreted that any right, privilege, or benefit of each party to receive notices and other documents under and in accordance with the applicable laws, regulations, treaties, or conventions, including but not limited to the Convention Relating to Civil Procedure concluded at the Hague on 1st day of March, 1954 and the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters concluded at the Hague on 15th day of November, 1965, is waived or limited.

22 Force Majeure

A delay in or failure of performance of each party hereto shall not constitute default under this Agreement nor give rise to any claim for damages if any to the extent such delay or failure is caused by *force majeure*, which means and includes without limitation fire, windstorms, typhoons or cyclones, hurricanes, lightning, landslide, earthquakes, *tsunami*, volcanic activity, floods, explosion, plagues, epidemics, inevitable accidents, acts of God, lockouts, strikes, sabotages, labor disputes, commotion, riots, insurrection, rebellion, military or usurped power, civil war, terrorism, *coup d'état*, revolution, hostilities, invasion, acts of foreign enemies, war (whether declared or undeclared), munitions, explosive material, ionizing radiation or contamination by radioactivity, failure or shortage of supply of labor, material, power or utility, transportation difficulty, embargoes, blockades, prohibition of export or import, refusal to issue an export or import license, legal restrictions, actions of the judicial or governmental authority or any *de jure* or *de facto* authority or ruler and any other justifiable or unforeseeable cause beyond the reasonable control of the party hereto affected. In the event that either party ceases to perform its obligations under this Agreement due to the occurrence of a Force Majeure event, such party shall: (a) immediately notify the other party in writing of such Force Majeure event and its expected duration; (b) take all reasonable steps to recommence performance of its obligations under this Agreement as soon as possible. In the event that any Force Majeure event delays a party's performance for more than ninety (90) days following notice by such party pursuant to this Agreement, then the Parties shall discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure event.

23 No Assignment

Neither this Agreement nor any of the rights and obligations hereunder may be assigned or transferred by a party hereto to any third party without prior written approval of the other party, which shall not be unreasonably withheld, except that no prior written consent is required in the event of assignment to an Affiliate or a successor in business to which this Agreement pertains. All of the terms, conditions, covenants, and agreements set forth herein shall inure to the benefit of, and be binding upon, any successor and any permitted assignees of the respective parties hereto.

24 No Waiver

In no event shall any obligation of each party hereto under this Agreement be discharged in whole or in part by waiver or renunciation unless such waiver or renunciation is made in writing and is signed by a duly authorized representative of the other party. No waiver by each party hereto with respect to any breach or default of the other party or with respect to any provision or condition of this Agreement shall be deemed to constitute either a waiver of any subsequent breach or default or continuing waiver with respect to the same or any other provision or condition of this Agreement, unless there is a written document to that express effect signed by a duly authorized representative of either party hereto, as the case may be.

25 Entirety and Amendment

This Agreement and the License Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and shall supersede any previous understandings or agreements relating thereto. This Agreement may be amended only by a written instrument duly signed by the authorized representative of each party hereto.

26 Severability

Should any provision of this Agreement be invalid, illegal or unenforceable in any respect, such provision shall be severed and the parties specifically intend that the remaining provisions shall continue as valid, legal and enforceable, and these provisions shall be integrated and interpreted in such a way as to give them maximum enforceability and validity under the applicable laws, while retaining the original intent of the parties with respect to such provisions.

27 Compliance with Laws

Each party hereto shall comply with all applicable laws, rules, regulations, orders, licenses, consents, and decrees of any governmental, local, municipal, or any other authority, agency or body and all other requirements having force and applicable at any time with affect in any manner to this Agreement or each party's performance thereunder. In case of failure, the failing party shall bear any additional cost resulting from such non-compliance, including costs for any remedial work. The provisions of this Article 27 shall also apply for the License Agreement.

28 No License

The parties hereto acknowledge and agree that this Agreement, but not the License Agreement, shall not be construed as granting or conferring any rights by license, estoppel or otherwise, expressly, impliedly, under any patent, utility model right, design patent, trademark, copyright, trade secret, or other proprietary rights of each party, or for any invention, discovery or improvement made, conceived or acquired prior to or after the date of this Agreement by each party other than those rights expressly granted or conferred under this Agreement. All licenses granted by Wakamoto to Harrow shall be governed by the License Agreement.

29 Independent Contractors

The parties hereto acknowledge and agree that this Agreement shall not be construed nor interpreted as creating any franchise, agency, partnership, joint venture, consortium or employment relationship, or similar thereto, between the parties hereto. The relationship between the parties hereto under this Agreement shall be solely that of independent contractors. Neither party shall have nor hold itself out as having any right, power or authority to assume, create or incur any cost, expenses, liability or obligation on behalf of the other party.

30 No Binding

The parties hereto acknowledge and agree that this Agreement shall not be construed or interpreted as binding each party hereto to enter into certain contractual, business, or any other relationship than the same expressly provided herein and that each party hereto shall have full option to or not to enter into such other relationship with the other party at such party's sole discretion.

31 Heading

The heading to the provisions of Articles of this Agreement have been inserted only to facilitate reference and shall not be taken as being of any significance whatsoever in the construction and interpretation of this Agreement.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the parties hereto have executed this Agreement to be signed by their duly authorized representatives in duplicate, each copy to be considered an original, as of the Effective Date first above written and each party respectively retains one (1) original copy hereof.

HARROW HEALTH, INC.

WAKAMOTO PHARMACEUTICAL CO., LTD.

/s/ Mark L. Baum

By: Mark L. Baum

Title: CEO

Date: August 16, 2021

/s/ Norihisa Kojima

By: Norihisa Kojima

Title: President & CEO

Date: August 18, 2021

Annex 1

Basic Conditions for the Product to be sold by Wakamoto and to be purchased by Harrow

Product Name	Triamcinolone Acetonide*, MAQAID, ophthalmic injection 40 mg
Supply Price	<p>*An aseptically filled sterile powder that is admixed with a liquid carrier medium prior to administration.</p> <p>1) [***] JPY/vial (CIF) for the first [***] vials sold annually</p> <p>2) [***] JPY/vial (CIF) for vials over [***] vials sold annually</p> <p>*Batch Quantity is around [***] vials/batch</p> <p>*Minimum purchase unit is [***] vials [***]batches)/ shipment</p> <p>*If any generic version of the Product begins to be marketed and sold in the above Indications and Territory, or if the price of any branded product that is a triamcinolone acetonide ophthalmic injection 40 mg/ml is reduced by more than [***], this Supply Price should be negotiated and be finally decided by Wakamoto and Harrow.</p> <p>*Harrow bear the product liability coverage of the Product in the territory.</p> <p>The rate of exchange to be used in computing the amount of currency equivalent in United States Dollars shall be the monthly average exchange rate between each currency of origin and U.S. Dollars as reported by Bloomberg or an equivalent resource as agreed by the Parties</p>

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

LICENSE AGREEMENT

BY AND BETWEEN WAKAMOTO PHARMACEUTICAL CO., LTD.

AND

HARROW HEALTH, INC.

AUGUST 18, 2021

LICENSE AGREEMENT

This License Agreement (this "Agreement") is made effective as of the day of August, 2021 (the "Effective Date") by and between Wakamoto Pharmaceutical Co., Ltd. Japanese corporation having its principal place of business at 2-2-2, Nihonbashi Honcho, Chuo-ku, Tokyo, 103-8330, Japan, including its Affiliates ("Wakamoto"), and Harrow Health, Inc., a Delaware corporation having its principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 USA, including its Affiliates ("Harrow"). Wakamoto and Harrow are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

Whereas, Harrow is a pharmaceutical company engaged in the research, development and commercialization of products useful in the amelioration, treatment or prevention of ophthalmic diseases and conditions.

Whereas, Wakamoto is a pharmaceutical company that has developed and commercialized in certain countries a triamcinolone acetonide ophthalmic 40 mg injection formulation (an aseptically filled sterile powder that is admixed with a liquid carrier medium prior to administration, including all modifications to the current formulation) (the "Product") that can be potentially used for one or more ophthalmic indications.

Whereas, Wakamoto is capable of commercially manufacturing the Product.

Whereas, Harrow wishes to be granted, and Wakamoto desires to grant, an exclusive license under the Product, its formulation, and associated intellectual property in order to obtain regulatory approval and commercialization of the Product in the Territory (as defined below) for the Licensed Indications (as defined below).

Whereas, Wakamoto wishes to supply the Product for Harrow and Harrow wishes to purchase the Product from Wakamoto for commercialization in the Territory.

Whereas, Wakamoto and Harrow are concurrently executing a Basic Sale and Purchase Agreement as of the Effective Date regarding the supply of the Product (the "Supply Agreement").

Now, therefore, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1. DEFINITIONS

1.1 "Accounting Standards" means United States Generally Accepted Accounting Principles ("GAAP"); provided, that, to the extent that a Party adopts International Financial Reporting Standards ("IFRS"), Accounting Standards shall mean IFRS in either case, consistently applied.

1.2 “Affiliate” means, with respect to a particular Party, a Person that controls, is controlled by, or is under common control with, such Party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, by contract, as a general partner or manager or otherwise.

1.3 “Applicable Law” means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including the U.S. Food, Drug and Cosmetic Act, (21 U.S.C. §301 et seq.) (“FDCA”), Public Health Service Act, (42 U.S.C. §201 et seq.) (“PHSA”), Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), GCP, GLP, and GMP, all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder and including any foreign equivalents of any of the foregoing.

1.4 “Business Day” means a day other than Saturday, Sunday or any other day on which commercial banks located in New York City, New York, U.S., or Tokyo, Japan, are obligated by Applicable Law to close.

1.5 “Calendar Year” means the twelve (12) month period ending on December 31; provided, however, that (a) the first Calendar Year of the Term, shall begin on the Effective Date and end on December 31, 2021; and (b) the last Calendar Year of the Term shall end on the effective date of expiration or termination of this Agreement.

1.6 “Change of Control” means, with respect to a Party (an “Acquired Party”), the occurrence of any of the following events from and after the Effective Date: (a) any Person or group of Persons becomes the beneficial owner (directly or indirectly) of voting securities representing more than fifty percent (50%) of the total voting power of all of the then-outstanding voting securities of such Acquired Party; (b) the consummation of a merger, consolidation, recapitalization, or reorganization of such Acquired Party, other than any such transaction, which results in stockholders or equity holders of such Acquired Party, or an Affiliate of such Acquired Party, immediately prior to such transaction owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) the sale or other transfer to a Third Party of all or substantially all of such Acquired Party’s assets which relate to this Agreement. Notwithstanding the foregoing, an investment transaction by venture capital or other financial investors not engaged in the pharmaceutical or biotechnology business and not otherwise affiliated with a pharmaceutical or biotechnology company, the purpose of which is to raise capital for a Party for working capital purposes only, shall not be deemed to be a Change of Control for purposes of this Agreement.

1.7 “Clinical Trial” means any human clinical study, veterinary clinical study, bioequivalence study or trial of Products in the Field in the Territory.

1.8 “Commercialize” or “Commercialization” means all activities, whether initiated or conducted prior to or following Regulatory Approval for a Product in the Field and in the Territory, undertaken in support of the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Product to customers) of the Product, including: (a) sales force efforts, detailing, advertising, marketing and preparation and use of Promotional Materials, sales and distribution, pricing, contracting managed markets and medical affairs, including activities with respect to medical education and the distribution of medical information, clinical science liaison activities, and the conduct of investigator initiated sponsored research programs and health economics and outcomes research, and (b) product security activities, including enhancing supply chain security, implementing brand protection technologies, intelligence gathering, forensic analysis, customs recordation, and anti-counterfeiting enforcement action, such as taking Internet countermeasures, collaborating with law enforcement and seeking criminal restitution. “Commercialize” means to engage in Commercialization activities.

1.9 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended, or considerations to be undertaken, by a Party or its Affiliate with respect to any objective, activity or decision to be undertaken hereunder, reasonable, good faith efforts to accomplish such objective, activity or decision as used by a company in the industry of a similar size and profile as such Party to accomplish a similar objective, activity or decision, it being understood that with respect to Development and Commercialization of the Product, such efforts shall be consistent with those efforts to develop or commercialize, as the case may be, a product owned by such company or to which it has rights, which product is of similar market potential as the Product, and at a similar stage of its product life, taking into account the establishment of the product in the marketplace, the competitiveness of the marketplace, the proprietary position of the product, the regulatory status involved, and the profitability of the product, in the case of each such factor as in existence and as reasonably projected to be in existence during the Term of this Agreement, as well as other relevant factors including without limitation efficacy and patient safety, which efforts shall correspond at least to the same type (quality and quantity) of channels, methods, investments, and staff (including, without limitation, sales force), which are used by reputable pharmaceutical companies that are engaged in pharmaceutical business in the marketing of their own products with a similar potential in the Territory.

1.10 “Control” or “Controlled” means, with respect to any Information, Know-How, Patent or other intellectual property right, the possession (including ownership) by a Party or its Affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense to such Information, Know- How, Patent or other intellectual property right without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any Third Party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license or sublicense. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to “Control” any Information, Know-How, Patent or other intellectual property right that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such Acquired Party after the Effective Date as a result of such Change of Control unless (a) prior to the consummation of such Change of Control, such Acquired Party or any of its Affiliates also Controlled such Information, Know-How, Patent or other intellectual property right, or (b) the Information, Know-How, Patent or other intellectual property right owned or in-licensed by such Third Party were not used in the performance of activities under this Agreement prior to the consummation of such Change of Control, but after the consummation of such Change of Control, the Acquired Party or any of its Affiliates determines to use or uses any such Information, Know-How, Patent or other intellectual property right in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases ((a) and (b)), such Information, Know-How, Patent or other intellectual property right will be “Controlled” by such Party for purposes of this Agreement.

1.11 “Development” means all research, non-clinical and clinical drug development activities, including toxicology, pharmacology, and other non-clinical efforts, statistical analysis, formulation development, delivery system development, statistical analysis, the performance of Clinical Trials, or other activities reasonably necessary in order to obtain Regulatory Approval of Products in the Field in the Territory. “Development” shall exclude all Commercialization activities and Regulatory Activities. When used as a verb, “Develop” means to engage in Development activities.

1.12 “Exploit” or “Exploitation” means to research, distribute, import, export, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve, or otherwise dispose of or perform Regulatory Activities.

1.13 “FDA” means the U.S. Food and Drug Administration, or any successor agency thereto.

1.14 “FFDCA” means the Federal Food, Drug and Cosmetic Act under United States Code, Title 21, as amended.

1.15 “Field” means diagnosis, treatment, amelioration, or prevention of any and all ophthalmic diseases or indications, including any symptoms thereof, human or animal.

1.16 “Force Majeure” means any event beyond the reasonable control of the affected Party including embargoes; war or acts of war, including terrorism, insurrections, riots, or civil unrest; strikes, lockouts or other labor disturbances; epidemics, pandemics, the spread of infectious diseases, and quarantines; fire, floods, earthquakes, tsunami or other acts of nature; or acts, omissions or delays in acting by any Governmental Authority (including the refusal of the competent Governmental Authorities to issue required Regulatory Approvals due to reasons other than the affected Party’s or its Affiliate’s negligence or willful misconduct or breach of any term or condition of this Agreement or any other cause within the reasonable control of the affected Party or its Affiliates) and failure of plant or machinery (provided, that, such event or failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances).

1.17 “Good Clinical Practices”, “GCP” or “cGCP” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines adopted by the International Conference on Harmonization (“ICH”), titled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices any other Regulatory Authority applicable to the Territory, as they may be updated from time to time.

1.18 “Good Laboratory Practices”, “GLP”, or “cGLP” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by any other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

1.19 “Good Manufacturing Practices”, “GMP”, or “cGMP” means the then-current good manufacturing practices required by the FDA, as set forth in the FDCA, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the U.S and the regulations promulgated thereunder, in each case as they may be updated from time to time.

1.20 “Governmental Authority” means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.21 “Harrow Invention” means any Invention that is made solely by Harrow’s own employees, agents, or independent contractors in the course of conducting its activities under this Agreement or otherwise relating to the Exploitation of Products in the Field in the Territory, together with all intellectual property rights therein.

1.22 “Harrow Know-How” means all Know-How Controlled by Harrow during the Term that is necessary or useful to Exploit or Products in the Field. Harrow Know-How includes all Harrow Inventions but excludes any Information contained within a Harrow Patent.

1.23 “Harrow Patents” means all Patents Controlled by Harrow during the Term that are necessary or useful to Exploit Products in the Field in the Territory. As of the Effective Date there are no existing Harrow Patents in the Territory.

1.24 “Harrow Technology” means all Harrow Know-How and Harrow Patents.

1.25 “IND” means (a) an Investigational New Drug application as defined in the FDCA, as amended, and applicable regulations promulgated hereunder by the FDA, (b) a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction, or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in such jurisdiction.

1.26 “Indication” means a human or animal disease or medical condition which is approved by a Regulatory Authority to be included as a discrete claim (as opposed to a subset of a claim) in the Labeling of a Product based on the results of a separate Clinical Trial sufficient to support Regulatory Approval of such claim.

1.27 “Information” means information, inventions, discoveries, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Governmental Authority or patent office, data, including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

1.28 “Inventions” means any and all inventions, discoveries and developments, whether or not patentable, made, conceived or reduced to practice in the course of performance of this Agreement or otherwise relating to the Exploitation of Products in the Field in the Territory, whether made, conceived or reduced to practice solely by, or on behalf of, Wakamoto, Harrow or the Parties jointly.

1.29 “Joint Know-How” means all Information and Inventions jointly Controlled by Wakamoto and Harrow during the Term that is/are necessary or useful to Exploit the Product in the Field in the Territory. Joint Know-How excludes any Information contained within a Joint Patent.

1.30 “Joint Patents” means all Patents jointly Controlled by Wakamoto and Harrow during the Term that are necessary or useful to Exploit the Product in the Field in the Territory. As of the Effective Date there are no existing Joint Patents in the Territory.

1.31 “Joint Technology” means, collectively, all Joint Know-How and Joint Patents.

1.32 “Know-How” means, with respect to a Party, all Information and Inventions Controlled by such Party. Know-How excludes any Information contained within a Party’s Patents.

1.33 “Labeling” means the healthcare professional information or patient information that is part of a Product’s Regulatory Approval Application or Regulatory Approval, including the package insert, medication guides, summary of product characteristics, patient information leaflets, company core safety information and company core data sheet.

1.34 “Licensed Indications” means: (a) Visualization of vitreous body during vitrectomy; (b) Treatment for diabetic macular edema by intravitreal injection; (c) Alleviation of macular edema associated with diabetic macular edema, retinal vein occlusion or non-infectious uveitis by sub-tenon’s injection; and (d) any other ophthalmic related condition, human or animal.

1.35 “Manufacture” means all activities related to the manufacturing the Product, or any ingredient thereof, for Development, Commercialization and Regulatory Activities, including the production, manufacture, processing, filling, finishing, and holding of Products and any intermediate thereof, labeling, packaging, Product testing, release of Products or any ingredient thereof, quality assurance activities related to isolation and manufacturing and release of Products, and any stability tests and regulatory activities related to any of the foregoing. When used as a verb, “Manufacture” means to engage in manufacturing activities.

1.36 “NDA” means a New Drug Application or supplemental New Drug Application as contemplated by Section 505(b) of the FDCA, as amended, and the regulations promulgated thereunder, submitted to the FDA pursuant to Part 314 of Title 21 of the U.S. C.F.R., including any amendments thereto. References herein to NDA shall include, to the extent applicable, any comparable applications filed in countries in the Territory outside the U.S.

1.37 “Net Sales” means, with respect to any Product, the gross amounts invoiced or received by Harrow, its Affiliates and its respective sublicensees for sales of such Product to unaffiliated Third Parties, less the following deductions:

(a) customary cash, trade or quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local government;

(b) credits, rebates or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Product, including in connection with recalls, and the actual amount of any retroactive price reductions;

(c) packaging, freight, postage, shipping, transportation, warehousing, handling and insurance charges, in each case actually allowed or paid for delivery of such Product, and any customary payments with respect to the Product actually made to wholesalers or other distributors, in each case actually allowed or paid for distribution and delivery of Product, to the extent billed or recognized;

(d) taxes (other than income taxes), duties, tariffs, mandated contribution or other governmental charges levied on the sale of such Product, including VAT, excise taxes, sales taxes and that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended), that Harrow, its Affiliates or (sub)sublicensees, as applicable, allocate to sales of such Product in accordance with Harrow’s, its Affiliates’ or (sub)sublicensees’ standard policies and procedures consistently applied across its products, as applicable; and

(e) any sales, credits or allowances given or made with respect to Products for indigent patient, Clinical Trial and any unpaid compassionate or named patient, charitable or humanitarian programs.

Notwithstanding the foregoing, dispositions of any Product by Harrow to its Affiliates or by Harrow or its Affiliates to its respective sublicensees, in each case, for resale shall not be considered to be a sale for purposes of the definition of Net Sales hereunder unless such Affiliate end customer or sublicensee end customer is the last Person in the distribution chain of the Product. In any event, any amounts received or invoiced by Harrow, its Affiliates, or its sublicensees shall be accounted for only once. For purposes of determining Net Sales, a Product shall be deemed to be sold when recorded as a sale by Harrow, its Affiliates or its respective sublicensees in accordance with the applicable Accounting Standards. For clarity, a particular deduction may only be accounted for once in the calculation of Net Sales. Net Sales shall exclude any samples of Product transferred or disposed of at no expense for promotional or educational purposes. For the avoidance of doubt, and for all purposes under this Agreement, Net Sales shall be accounted for in accordance with standard accounting practices, as practiced by Harrow its Affiliates or its respective sublicensees in the relevant country in the Territory, but in any event in accordance with the applicable Accounting Standards, as consistently applied in such country in the Territory.

1.38 “Patents” means all: (a) patents, including any utility or design patent; (b) patent applications, including provisional, substitutions, divisional, continuations, continuations in-part or renewals; (c) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues and re-examinations; (d) other patents or patent applications claiming priority directly or indirectly to: (i) any such specified patent or patent application specified in (a) through (c), or (ii) any patent or patent application from which a patent or patent application specified in (a) through (c) claim direct or indirect priority; (e) inventor’s certificates; (f) other rights issued from a Governmental Authority similar to any of the foregoing specified in (a) through (e); and (g) in each of (a) through (f), whether such patent, patent application or other right arises in the U.S. or any other jurisdiction in the Territory.

1.39 “Patent Term Extension” means any term extensions, supplementary protection certificates and equivalents thereof offering patent protection beyond the initial term with respect to any issued patents.

1.40 “Payments” is defined in Section 7.3(a).

1.41 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.42 “Pricing Approval” means any approval, agreement, determination or decision by a Governmental Authority establishing prices that can be charged and/or reimbursed for a Product in a jurisdiction where the applicable Governmental Authority or Regulatory Authority approves or determines the pricing of pharmaceutical products.

1.43 “Product” is defined in the preamble of this Agreement.

1.44 “Product Complaint” means any Information that comes to the attention of either Party, its Affiliates or its sublicensees, concerning any dissatisfaction regarding a Product of such a nature and magnitude that it is required under the Applicable Law to be collected, maintained and reported to a Regulatory Authority, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

1.45 “Product Liabilities” means all losses, damages, fees, expenses and other liabilities asserted by any Third Parties against a Party and resulting from or relating to human use of Products, including use in Clinical Trials or Commercialization of the Products or Regulatory Activities, in the Territory during the Term, but excluding all losses, damages, fees, expenses and other liabilities that are a result of a Party’s, its Affiliates’ or its sublicensee’s gross negligence, willful misconduct or breach of such Party’s obligations under this Agreement, including its representations and warranties made hereunder. For the avoidance of doubt, Product Liabilities include reasonable attorneys’ and experts’ fees and expenses relating to any claim or potential claim against a Party, its Affiliate, or its sublicensee. Product Liabilities shall not include any losses, damages, fees, expenses and other liabilities associated with recalls and/or the voluntary or involuntary withdrawal of Products.

1.46 “Promotional Materials” means all written, printed, graphic, electronic, audio or video presentations of information, including journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, disease awareness materials, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items, if appropriate) that, in each case, are permitted under Applicable Law, and intended for use or used by or on behalf of Harrow , its Affiliates or its sublicensees in connection with the Commercialization of a Product in the Territory.

1.47 “Regulatory Activities” means all activities, other than Development and Commercialization activities, that are reasonably necessary in order to obtain and maintain Regulatory Approval of Products in the Field in the Territory, including but not limited to (a) the preparation, filing, and maintenance of Regulatory Materials, including the filing of annual updates, and (b) the conduct of post-marketing Studies.

1.48 “Regulatory Approval” means any approval (including supplement, amendment, pre- and post-approval), Pricing Approvals and reimbursement approvals, licenses, registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other Government Authority, that is necessary for the Commercialization of Products under this Agreement in a particular country in the Territory.

1.49 “Regulatory Approval Application” means a NDA or any corresponding application for Regulatory Approval in the Territory, including, in each case, all supplements, amendments, variations, extensions and renewals thereof.

1.50 “Regulatory Authority” means any applicable Governmental Authority that holds responsibility for granting of Regulatory Approval for development and commercialization of the Product in a country or jurisdiction in the Territory, including in the U.S., the FDA; and in Canada, Health Canada.

1.51 “Regulatory Documentation” means, with respect to Products, all (a) Regulatory Materials, including all data contained therein and all supporting documents created for, submitted to or received from an applicable governmental agency or Regulatory Authority relating to such Regulatory Materials; and (b) other documentation or Information Controlled by a Party which is reasonably necessary in order to Exploit the Product in the Field in the Territory, including any registrations and licenses, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and Manufacturing records.

1.52 “Regulatory Materials” means, all documentation, correspondence, submissions and notifications submitted to or received from a Regulatory Authority in order to Exploit a Product in the Field in the Territory. For the avoidance of doubt, Regulatory Materials shall include, with respect to Products, all INDs, Regulatory Approval Applications, Regulatory Approvals (including Pricing Approvals), and amendments and supplements for any of the foregoing, as well as the contents of any minutes from meetings (whether in person or by audio conference or videoconference) with a Regulatory Authority.

- 1.53 “Supply Agreement” is defined in Section 6.2.
- 1.54 “Territory” means the United States of America and Canada, including their territories and possessions.
- 1.55 “Third Party” means a Person other than Wakamoto and Harrow and their respective Affiliates.
- 1.56 “Trademark” means Wakamoto’s MAQAID trademark.
- 1.57 “Wakamoto Invention” means any Invention that is made solely by Wakamoto’s own employees, agents, or independent contractors relating to the Exploitation of the Product in the Field in the Territory, together with all intellectual property rights therein.
- 1.58 “Wakamoto Know-How” means all Know-How Controlled by Wakamoto during the Term, which is necessary or useful to Exploit Products in the Field in the Territory. Wakamoto Know-How includes all Wakamoto Inventions but excludes any Information contained within a Wakamoto Patent.
- 1.59 “Wakamoto Patents” means all Patents Controlled by Wakamoto, during the Term that are necessary or useful to Exploit Products in the Field in the Territory. As of the Effective Date there are no existing Wakamoto Patents in the Territory.
- 1.60 “Wakamoto Technology” means, collectively, all Wakamoto Know-How and Wakamoto Patents.

ARTICLE 2. LICENSES

2.1 License from Wakamoto to Harrow. Subject to the terms and conditions of this Agreement, Wakamoto hereby grants to Harrow an exclusive (even as to Wakamoto) license in the Field in the Territory, with the right to grant sublicenses, to develop, promote, market, sell and distribute the Product for the Licensed Indications within the Territory. For the avoidance of doubt, manufacturing of Licensed Product is not included within the scope of the license as Wakamoto shall be responsible for manufacturing and providing Product to Harrow. The license grant in this Section 2.1 expressly includes: (i) a license of all Wakamoto Technology within the Field in the Territory; and (ii) a license of all of Wakamoto’s rights in Joint Technology within the Field in the Territory.

2.2 Sublicenses.

(a) Subject to the terms and conditions of this Agreement, Harrow shall have the right to grant sublicenses, through multiple tiers, under the rights granted by Wakamoto to Harrow under Section 2.1 to one or more Third Parties.

(b) Each sublicense shall refer to and be subordinate to this Agreement and, except to the extent the Parties otherwise agree in writing, any such sublicense must be consistent in all material respects with the terms and conditions of this Agreement. Harrow shall remain responsible for the performance of this Agreement and the performance of its sublicense hereunder.

(c) Upon an early termination of Harrow's license rights under this Agreement, Wakamoto shall offer any Third Party sublicensee under a sublicense granted by Harrow or its Affiliates pursuant to this Section 2.2 that was in effect on the effective date of termination of Harrow's license rights under this Agreement the right to enter into a license agreement directly with Wakamoto on substantially the same terms and conditions under which such rights and licenses were granted to such sublicensee, provided that such sublicensee (i) is not then in breach of its sublicense, (ii) agrees to comply with all the terms of this Agreement to the extent applicable to the rights sublicensed to it by Harrow, and (iii) such agreement does not impose any obligations upon Wakamoto that exceed the obligations of Wakamoto under this Agreement.

2.3 **No Implied Licenses.** No license or other right is or shall be created or granted hereunder by implication, estoppel, or otherwise. All licenses and rights are or shall be granted only as expressly provided in this Agreement. All rights not expressly granted by a Party under this Agreement are reserved by the Party and may not be used by the other Party for any purpose.

ARTICLE 3. DEVELOPMENT

3.1 **Harrow Development.** Harrow shall be solely responsible for: (a) all activities related to the Development of the Products in the Field in the Territory; and (b) all expenses, including Third Party expenses, related to such Development activities.

3.2 **Wakamoto Development.** Wakamoto shall be solely responsible for all activities related to the Manufacture of the Products in the Field for Development and Regulatory Activities in the Territory. Wakamoto's Manufacture of the Products for Commercialization shall be governed by the Supply Agreement.

3.3 **Development Diligence.** Harrow shall use Commercially Reasonable Efforts to Develop a Product for the Licensed Indications in the Territory. Harrow shall use commercially reasonable efforts to plan to initiate one or more Clinical Studies of the Product for the Licensed Indication(s) within 12 months from the Effective date of the Agreement, if such Clinical Studies are deemed necessary to obtain Regulatory Approval of the Licensed Product in the Territory.

3.4 **Supply of Product for Clinical Studies.** Wakamoto shall supply all Product for all Clinical Studies needed for Harrow's Development responsibilities. The cost for such Product to Harrow shall be [***] Japanese Yen/vial (CIF Newark International Airport (EWR), Incoterms (2020)).

3.5 **Transfer of Wakamoto Know-How.** Promptly following the Effective Date, and promptly during the Term upon such Wakamoto Know-How being obtained or generated by Wakamoto, Wakamoto shall provide to Harrow, at no additional expense and on an "as is" basis to Harrow, all Wakamoto Know-How as is necessary or useful to enable Harrow to conduct Development activities, Commercialization activities and Regulatory Activities under this Agreement or otherwise to practice the licenses granted to it under this Agreement, to the extent such Wakamoto Know-How has not previously been provided to Harrow. Notwithstanding the above, and except for its obligations under Section 3.2, Wakamoto shall not be responsible for any Development costs, including pre-IND consultation fees.

3.6 Records; Disclosure of Data and Results. In conformity with Applicable Law, standard pharmaceutical industry practices and the terms and conditions of this Agreement, each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to Development activities conducted pursuant to this Agreement; provided, that, in no instance shall such records be maintained for less than two (2) years following the end of the Calendar Year to which the records pertain.

ARTICLE 4. REGULATORY

4.1 Regulatory Responsibility. Harrow shall be solely responsible for preparing, filing and managing all Regulatory Materials with respect to Products in the Field in the Territory at its sole expense, shall own such Regulatory Materials and shall have sole discretion in determining the best regulatory strategy for obtaining approval of the Product. Harrow shall be responsible for payment of the drug application filing fees (i.e., the PDUFA fee in the United States and the corresponding new drug application fee for Health Canada) and shall be responsible for conducting all meetings and managing communications with the Regulatory Authorities in the Territory. Notwithstanding the above, Wakamoto shall fully cooperate with Harrow to the extent necessary for Harrow's submission and management of Regulatory Documentation, including but not limited to information relating to the Manufacture of the Product.

4.2 Adverse Event Reporting and Safety Data Exchange. During the Term, Harrow shall have the sole responsibility for the monitoring of all clinical experiences, maintaining the global safety database, safety monitoring, pharmacovigilance surveillance, compliance and filing of all required safety reports to Regulatory Authorities in the Territory, including annual safety reports, throughout the Development and Commercialization of the Products.

4.3 Regulatory Authority Communications Received by a Party. Each Party shall keep the other Party informed in a timely manner, compliant with the reporting requirements of Regulatory Authorities in the Territory, of the notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority and any regulatory authority outside of the Territory, including, but not limited to Japan's Pharmaceuticals and Medical Devices Agency (PDMA) under the authority of Ministry of Health, Labour and Welfare (MHLW), which: (a) raises any material concerns regarding the safety or efficacy of a Product; (b) indicates or suggests a potential material liability of Harrow to Third Parties in connection with a Product; (c) is reasonably likely to lead to a recall or market withdrawal of a Product; or (d) relates to expedited and periodic reports of adverse events with respect to a Product, or Product Complaints, and which may have a material impact on obtaining or maintaining Regulatory Approvals or the continued Commercialization of a Product, as then conducted. Wakamoto shall fully cooperate with and assist Harrow in complying with regulatory obligations and communications, including by providing to Harrow, in a timely manner after a request, such Information and documentation in Wakamoto's possession as may be necessary or helpful for Harrow to prepare a response to an inquiry from a Regulatory Authority.

4.4 Audits. If a Regulatory Authority notifies Wakamoto that it plans to conduct an inspection or audit of its facility or a facility under contract with it with regard to a Product in the Territory, then Wakamoto shall notify Harrow as soon as practicably possible after receipt of such notification of such audit or inspection and provide copies of any materials provided to it by the applicable Regulatory Authority; provided, that Wakamoto shall not be required to notify Harrow of audits or inspections that are of a routine nature or that do not relate to a Product, except where such audits result in communications or actions of such Regulatory Authority which would reasonably be expected to have an impact upon the Product. In addition, if a Regulatory Authority conducts an unannounced inspection or audit of Wakamoto's facility or a facility under contract with Wakamoto with regard to a Product in the Territory, then Wakamoto shall notify Harrow within [***] of commencement of such audit or inspection. Wakamoto shall cooperate with such Regulatory Authority and Harrow during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the Wakamoto shall promptly provide to Harrow), Wakamoto shall also provide Harrow with copies of any written communications received from Regulatory Authorities with respect to such facilities in a timely manner after receipt, to the extent such written communications relate to Products or the Manufacture thereof, and shall prepare the response to any such observations. Wakamoto shall provide Harrow with a copy of any proposed response to such communications and shall give good faith consideration to Harrow's reasonable comments with respect to such proposed response. Wakamoto agrees to conform its activities under this Agreement to any commitments made in such a response.

4.5 Confidentiality of Regulatory Materials. All Regulatory Materials prepared by Harrow and Wakamoto, respectively, shall be deemed Harrow and Wakamoto Confidential Information and subject to Article 11 of the Supply Agreement.

ARTICLE 5. COMMERCIALIZATION

5.1 Commercialization Activities. Subject to the terms and conditions of this Agreement, Harrow shall be solely responsible for all aspects of the Commercialization of Products in the Field in the Territory, including: (i) developing and executing a commercial launch and pre-launch plan, (ii) marketing and promotion; (iii) booking sales and distribution and performance of related services, including those described in Section 5.1(a); (iv) handling all aspects of order processing, invoicing and collection, inventory and receivables; (v) publications, (vi) providing customer support, including handling medical queries, and performing other related functions; (vii) conforming its practices and procedures in all respects to the Applicable Law relating to the marketing, detailing and promotion of Products in the Field in the Territory; and (viii) product security activities. Harrow shall be solely responsible for the review and approval of all Promotional Materials for compliance with Applicable Law, including submission, where appropriate, to the applicable Regulatory Authority. Except as otherwise provided in this Article 5, Harrow shall bear all of the expenses incurred in connection with all such Commercialization activities.

(a) **Sales and Distribution**. Harrow shall have the sole right and responsibility for handling all sales and distribution activities, including returns, order processing, invoicing and collection, distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Products to customers), and inventory and receivables for Products in the Field in the Territory. Wakamoto shall not accept orders for the purchase of Products from Third Parties or make sales of Products to Third Parties in the Field in the Territory for its own account or for Harrow's account. If Wakamoto receives any order for Products in the Field in the Territory, it shall refer such order to Harrow for acceptance or rejection. As a reference, estimated sales forecast of Products in the territory is shown in Annex 1 as just a sales goal without any guarantee that Harrow will achieve such goals, with Harrow's failure to achieve such estimated sales forecast not being a basis entitling Wakamoto to terminate this Agreement.

(b) **Booking Sales and Setting Pricing.** Harrow shall have the sole and exclusive right to book sales and determine all pricing of Products in the Territory, including (i) negotiating, establishing or modifying the terms and conditions regarding the sale of Products in the Field in the Territory, including any terms and conditions relating to or affecting (A) the price at which Products shall be sold, (B) discounts available to any Third Party payers (including managed care providers, indemnity plans, unions, self- insured entities, and government payer, insurance or contracting programs such as Medicare, Medicaid, or the U.S. Department of Veterans Affairs, or similar programs located in other countries of the Territory), (C) discounts attributable to payments on receivables, (D) distribution of Products, and (E) credits, price adjustments, or other discounts and allowances to be granted or refused; and (2) all activities relating to government price reporting with respect to Products in the Field in the Territory. Notwithstanding anything in this Agreement express or implied to the contrary, Wakamoto shall not have any right to direct, control, or approve Harrow's pricing of Products for the Territory. However, Harrow shall ask Wakamoto's opinion and pay attention enough to the determination of the price so as not to negatively affect the price of Product in Japan.

5.2 **Trademarks.** Except for the Trademark, Harrow shall be solely responsible, at its own expense, for all matters relating to the use of, and shall own, all trademarks, including all associated goodwill, used in the sale of Products in the Field in the Territory, including the selection, filing, prosecution, maintenance, defense and enforcement thereof. Notwithstanding the above, Wakamoto offers to Harrow the right to license the Trademark, along with all associated goodwill, on an exclusive basis (even as to Wakamoto) for use as the brand name of the Product in the Territory. Should Harrow elect to exercise this license right and use the Trademark as the brand name in the Territory, Harrow shall pay to Wakamoto a royalty in the amount of [***] percent [***] of its Net Sales. Payment of such amount shall be made within [***] following the end of each Calendar Quarter. Harrow agrees to use the Trademark consistent with guidelines that shall be provided by Wakamoto. Wakamoto shall be solely responsible, at its own expense, for the Trademark, including the selection, filing, prosecution, maintenance, defense and enforcement thereof.

5.3 **Commercialization Diligence.** Harrow shall use Commercially Reasonable Efforts to Commercialize the Product for the Licensed Indications for which Harrow receives Regulatory Approval in the Territory. Notwithstanding the preceding sentence, Harrow shall not be obligated to launch the Product in the event that it either does not have a sufficient supply of Product or in the event that in the opinion of Harrow's external patent counsel, launching the product would involve an unnecessary commercial patent infringement risk to Harrow.

ARTICLE 6.
MANUFACTURING AND SUPPLY

6.1 General Supply Terms. During the Term, Wakamoto shall have the sole and exclusive right, at its sole expense, to Manufacture Products for Harrow by manufacturing them by itself or entrusting the manufacturing to qualified contract manufacturer, and the sole responsibility for the Manufacturing of Products, in each case for purposes of Development, Commercialization and for the conducting of Regulatory Activities.

6.2 Supply Agreement. Harrow's purchase of Product from Wakamoto shall be governed by the Sale and Purchase Agreement that shall be simultaneously entered into on the Effective Date, ("Supply Agreement").

7.1 Milestones.

ARTICLE 7.
PAYMENTS

(a) Harrow shall make milestone payments to Wakamoto based on achievement of certain milestone events for Products as set forth in this Section 7.1. Harrow shall notify Wakamoto upon its achievement of each such milestone event and Harrow shall pay to Wakamoto the amounts set forth below within [***] after the achievement of the corresponding milestone event. Each milestone payment by Harrow to Wakamoto hereunder shall be payable only once and shall be non-refundable.

Milestone Number	Milestone Event	Milestone Payment (U.S. Dollars)
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***]	[***]
(iv)	[***]	[***]
	[***]	

(b) Notwithstanding the above, the payment of milestone (iii) above shall be conditioned on Wakamoto having supplied sufficient launch quantities of the Product to Harrow pursuant to the Supply Agreement no [***] after FDA final approval of the Product for such Licensed Indication.

7.2 Net Sales Milestones.

(a) As further consideration for the rights granted to Harrow, Harrow shall pay to Wakamoto the following milestones based upon its achievement of certain annual Net Sales within the Territory for the Product. Harrow shall furnish Wakamoto with a written statement specifying annual Net Sales and number of vials of the Product sold in the territory [***] after the end of each calendar year during the term of this Agreement, and then, Harrow shall notify Wakamoto if it has achieved each such milestone event and Harrow shall pay to Wakamoto the amounts set forth below [***] following the end of applicable calendar year upon satisfaction of the relevant annual net sales thresholds for the Licensed Product in the Territory as set forth in the table below. Each milestone payment by Harrow to Wakamoto hereunder shall be payable only once and shall be non-refundable. Multiple milestones can be achieved for the same calendar year.

Annual Net Sales of Products in the Territory	Milestone Payment (U.S. Dollars)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

7.3 Audit. Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of milestone payments under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of [***] from the end of the Calendar Year to which they pertain for examination at the expense of the requesting Party by an independent certified public accountant selected by the requesting Party and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of the financial reports and the correctness of payments furnished by the other Party pursuant to this Agreement. Any such auditor shall not disclose the other Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the other Party or the amount of payments due by the other Party under this Agreement. Any amounts shown to be owed but unpaid shall be paid [***] [***] from the accountant's report, plus interest (as set forth in Section 7.5 from the original due date). Any amounts shown to have been overpaid shall be refunded [***] from the accountant's report. The requesting Party shall bear the full expense of such audit, unless such audit discloses an underpayment by the other Party of [***] of the amount due, in which case the other Party shall bear the full expense of such audit. The audit rights set forth in this Section 7.4 shall survive the termination or expiration of this Agreement for one (1) year.

7.4 Late Payment/Currency Exchange. All payments due to a Party hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by such Party. The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars owed to a Party under this Agreement shall be the monthly average exchange rate between each currency of origin and U.S. Dollars as reported by Bloomberg or an equivalent resource as agreed by the Parties. If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party until the date of payment [***] over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by Applicable Law, whichever is lower.

ARTICLE 8.
INTELLECTUAL PROPERTY MATTERS

8.1 Ownership of Inventions.

Harrow and Wakamoto represent, warrant, and covenant that as of the Effective Date of this Agreement with respect to Harrow Inventions and Wakamoto Inventions in the Territory:

(a) Harrow shall solely own all Harrow Inventions.

(b) Wakamoto shall solely own all Wakamoto Inventions.

(c) Subject to Article 2 of this Agreement, the Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of each Party in the course of performing activities under this Agreement, or otherwise relating to the Exploitation of Products in the Field in the Territory together with all intellectual property rights therein ("Joint Inventions").

(d) Inventorship shall be determined in accordance with U.S. patent laws.

(e) During the term of this Agreement, in the event that Wakamoto, either by itself or with a Third Party, develops an injectable ophthalmic product containing [***] as an active pharmaceutical ingredient that is different from the Product and will require a separate NDA (a "New Product"), Wakamoto, either by itself or through a Third Party, shall not Exploit such New Product in the Territory to Harrow's detriment. In the same way as the above, Harrow, either by itself or with a Third Party, develops an injectable ophthalmic product containing [***] as an active pharmaceutical ingredient that is different from the Product and will require a separate registration out of the Territory, Harrow, either by itself or through a Third Party, shall not Exploit such products regarded equal to New Product out of the Territory to Wakamoto's detriment.

8.2 Disclosure of Inventions. Both Harrow and Wakamoto shall promptly disclose to the other party any of their own Inventions, namely Harrow Inventions and Wakamoto Inventions, during the Term. With respect to any Joint Inventions, each Party shall promptly disclose to the other Party any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing the Joint Inventions, and all Information relating to such inventions to the extent necessary for the use of such Joint Technology and, to the extent patentable, for the preparation, filing and maintenance of any Patent with respect to such Invention.

8.3 Prosecution of Patents.

(a) **Wakamoto Patents.** Except as otherwise provided in this Section 8.3(a), Wakamoto shall have the first right and authority, at its own expense, to prepare, file, prosecute and maintain the Wakamoto Patents. Wakamoto shall provide Harrow a reasonable opportunity to review and comment on its efforts to prepare, file, prosecute and maintain Wakamoto Patents in the Territory, including by providing Harrow with a copy of material communications from any patent authority regarding any Wakamoto Patent, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Wakamoto shall consider Harrow's comments regarding such communications and drafts in good faith. If Wakamoto determines in its discretion to abandon or not maintain any Wakamoto Patent that is being prosecuted or maintained by Wakamoto in the Territory, then Wakamoto shall provide Harrow with written notice of such determination within a period of time reasonably necessary to allow Harrow to determine, in its discretion, its interest in such Wakamoto Patent (which notice by Wakamoto shall be given [***] prior to the final deadline for any pending action or response that may be due with respect to such Wakamoto Patent with the applicable patent authority). If Harrow provides written notice expressing its interest in obtaining ownership of such Wakamoto Patent, (i) Wakamoto shall transfer to Harrow the control of such Wakamoto Patent in the Territory through the mutual discussion between Harrow and Wakamoto to determine the transfer (e.g., its scope, its value, etc.), (ii) Harrow will thereupon have the right, but not the obligation, to assume the prosecution and maintenance thereof at Harrow's sole cost and expense (each, a "Harrow Assumed Patent"), through patent counsel or agents of its choice; and (b) Wakamoto shall promptly deliver to Harrow copies of all necessary files related to any Harrow Assumed Patents with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for Harrow to assume such activities, at Harrow's request.

(b) **Harrow Patents.** Harrow shall have the sole right and authority, at its own expense, to prepare, file, prosecute and maintain the Harrow Patents.

(c) **Joint Patents.** Except as otherwise provided in this Section 8.3(c), Harrow shall have the primary right and authority, to prepare, file, prosecute and maintain the Joint Patents in the Territory at its own expense using patent counsel that is reasonably acceptable to Wakamoto. Harrow shall provide Wakamoto with a reasonable opportunity to review and comment on such efforts regarding such Joint Patent, including by providing Wakamoto with a copy of material communications from any patent authority in such country(ies) in the Territory regarding such Joint Patent, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Harrow shall consider Wakamoto's comments regarding such communications and drafts in good faith. If Harrow determines in its sole discretion to abandon or not maintain any Joint Patent in any country(ies) of the Territory, then Harrow shall provide Wakamoto with written notice of such determination within a period of time reasonably necessary to allow Wakamoto to determine its interest in such Joint Patent (which notice from Harrow shall be given [***] prior to any final deadline for any pending action or response that may be due with respect to such Joint Patent with the applicable patent authority). In the event Wakamoto provides written notice expressing its interest in obtaining such Joint Patent(s), (a) Harrow shall assign and transfer to Wakamoto the ownership of, and interest in, such Joint Patent in the applicable jurisdiction in the Territory on behalf of Wakamoto through the mutual discussion between Harrow and Wakamoto to determine the transfer (e.g., its scope, its value, etc.); (b) Wakamoto will thereupon have the right, but not the obligation, to assume the prosecution and maintenance thereof at Wakamoto's sole cost and expense (each, a "Wakamoto Joint Assumed Patent"), through patent counsel or agents of its choice; and (c) Harrow shall promptly deliver to Wakamoto copies of all necessary files related to any Wakamoto Joint Assumed Patents with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for Wakamoto to assume such activities, at Wakamoto's request. Harrow shall cooperate with Wakamoto for assignment and transfer of such Joint Patent(s) in such country. Wakamoto shall have the primary right and authority, to prepare, file, prosecute and maintain the Joint Patents outside of the Territory at its own expense.

(d) **Cooperation in Prosecution.**

(i) Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts in the Territory provided above in Sections 8.3(a) and (c), including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions as set forth below. Such assistance and cooperation shall include making a Party's inventors and other scientific advisors reasonably available to assist the other Party's Patent preparation, filing, prosecution and maintenance efforts.

(ii) All communications between the Parties relating to the preparation, filing, prosecution or maintenance of Wakamoto Patents and Joint Patents, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information and subject to the confidentiality provisions of Article 10.

(iii) Assignments in Wakamoto Patents and Joint Patents shall be effected as follows: (1) employees or agents of Wakamoto that are named as inventors on Wakamoto Patents shall assign their interest in such Patents to Wakamoto; and (2) employees or agents of Harrow or Wakamoto that are named as inventors on Joint Patents shall assign their interest in such Patents to their respective employer.

8.4 Patent Term Extensions in the Territory.

(a) Harrow shall have the right to decide for the Parties on which, if any, of the Patents within Wakamoto Patents and Joint Patents in the Territory for which the Parties should seek Patent Term Extensions; provided, that, Harrow shall reasonably consider in good faith Wakamoto's position in connection therewith. Subject to the foregoing, Harrow shall be responsible for applying for the Patent Term Extension, unless, with respect to Wakamoto Patents, the applicable patent authority requires Wakamoto to file such application and if Harrow wishes Wakamoto to file such application, Harrow shall be responsible for paying all governmental fees and Wakamoto's documented external costs for such Wakamoto filed Patent Term Extensions. Wakamoto shall cooperate fully with Harrow in making such filings or actions, for example and without limitation, making available all required regulatory data and information and executing any required authorizations to apply for such Patent Term Extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which Patent Term Extensions are filed pursuant to this Section 8.4 shall be entirely borne by Harrow.

(b) Harrow shall have the sole right and authority, at its own expense, to seek Patent Term Extensions with respect to the Harrow Patents.

8.5 Patent Listing; Compendia Listing. Harrow shall have the right to (i) file appropriate information with the FDA in the U.S. listing any Wakamoto Patents, Harrow Patents or Joint Patents in the FDA's Orange Book; and (ii) with respect to other countries in the Territory, file appropriate information with the applicable Regulatory Authority listing any Wakamoto Patents, Harrow Patents or Joint Patents in the Patent listing source in such country in the Territory, if any. Upon request of Harrow, and to the extent required by any Applicable Laws, Wakamoto shall fully cooperate with Harrow to effectuate the above listing requirements.

8.6 Infringement of Patents by Third Parties.

(a) **Notification.** Each Party shall promptly notify the other Party in writing of any existing, alleged or threatened infringement of Wakamoto Patents or Joint Patents in the Field in the Territory of which it becomes aware, and shall provide all Information in such Party's possession or Control demonstrating such infringement.

(b) **Infringement of Wakamoto Patents or Joint Patents.**

(i) Harrow shall have the first right, but not the obligation, at its own expense, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened infringement of Wakamoto Patents or Joint Patents, subject to Section 8.6(b)(ii) through 8.6(b)(v), below.

(ii) Harrow shall notify Wakamoto of its election to take any action in accordance with Section 8.6(b)(i) within the earlier of: (1) [***] after the first notice under 8.6(a); or (2) [***] before any time limit set forth in an Applicable Law or regulation. In the event Harrow does not so elect, Harrow shall so notify Wakamoto in writing, and Wakamoto shall have the right to commence a suit or take action to enforce the applicable Patent against such Third Party perpetrating such infringement in the Territory at its own expense. If one Party elects to bring suit or take action against the infringement, then the other Party shall have the right, prior to commencement of the trial, suit or action, to join any such suit or action.

(iii) Each Party shall provide to the Party enforcing any such rights under this Section 8.6(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any important aspects of such enforcement including determination of material litigation strategy, filing of dispositive papers to the competent court.

(iv) The enforcing Party shall have the sole right to settle any claim, suit or action that it brought under this Section 8.6(b) involving Wakamoto Patents or Joint Patents without the prior written consent of the other Party unless such settlement will (a) impose any liability or obligation on such other Party, (b) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the subject matter included under the rights and licenses granted to such other Party under this Agreement, or (c) otherwise materially affect the licenses or other rights granted to such other Party hereunder adversely in any respect.

(v) The Party not bringing an action with respect to infringement in the Territory under this Section 8.6(b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action. If the non-enforcing Party requests that the Parties be jointly represented by the same outside counsel, the enforcing Party shall have the right to consent to such joint representation of the Parties, such consent not to be unreasonably withheld, delayed or conditioned. For clarity, the enforcing Party can withhold its consent to such joint representation where it has a good faith basis to believe there is a conflict between the Parties.

(c) **Infringement of Harrow Patents.** For any and all infringement of any Harrow Patent, Harrow shall have the sole and exclusive right, but not the obligation, to bring, at Harrow's expense and in its sole control, an appropriate suit or other action against any person or entity engaged in such infringement of the Harrow Patent. Wakamoto shall provide Harrow reasonable assistance in such enforcement, at Harrow's reasonable request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. Harrow shall retain one hundred percent (100%) of any recovery in connection with such suit or other action (after reimbursing Wakamoto for any of its expenses in connection with its assistance provided in accordance with this Section 8.6(c)).

(d) **Allocation of Proceeds.** If either Party recovers monetary damages from any Third Party in a suit or action brought under Sections 8.6(b), 8.7 or 8.8 related to any alleged Product Infringement, whether such damages result from the infringement of Wakamoto Patents or Joint Patents, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, action or license, and any remaining amounts shall be retained by the Party who has managed such litigation, action or license.

8.7 Infringement of Third Party Rights in the Territory.

(a) **Notice.** If any Product used or sold by Harrow or its sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party.

(b) **Defense.** Harrow shall have the first right, but not the obligation, at its own expense, to defend any such Third Party claim or assertion of infringement of a Patent as described in Section 8.7(a) above. If Harrow does not commence actions to defend such claim within [***] after it receives notice thereof or if Harrow discontinues the defense of any such action after filing, then to the extent allowed by Applicable Law, Wakamoto shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice, at Wakamoto's expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney. Any awards or amounts received in bringing any such action shall be first allocated to reimburse each Party's expenses in such action, and any remaining amounts shall be retained by the defending Party. Notwithstanding the above, at all times during the Term if, as part of obtaining Regulatory Approval for the Product in the United States, there is so called Hatch Waxman litigation where Harrow will be the defendant in such litigation, then Harrow shall be solely responsible for managing the litigation, including selection of counsel, and shall be responsible for all associated costs, including external legal fees.

(c) **Settlement; Licenses.** The defending Party shall have the sole right to settle any claim, suit or action that it brought under this Section 8.7 unless such settlement will (a) impose any liability or obligation on such other Party, (b) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the subject matter included under the rights and licenses granted to such other Party under this Agreement, or (c) otherwise materially affect the licenses or other rights granted to such other Party hereunder adversely in any respect. In the event that it is determined by any court of competent jurisdiction or Harrow reasonably determines (in the opinion of independent patent counsel) that the Exploitation of a Product in the Territory, conducted in accordance with the terms and conditions of this Agreement, infringes any patent, copyright, trademark, data exclusivity right or trade secret right arising under Applicable Law of any Third Party, the Parties shall use Commercially Reasonable Efforts to, at Harrow's discretion: (i) procure a license from such Third Party authorizing Harrow to continue to conduct such activities (in which case Section 8.6 shall apply); or (ii) modify such activities so as to render it non-infringing. In the event that Harrow, after using Commercially Reasonable Efforts, determines that neither of the foregoing alternatives is available or commercially feasible, Harrow may, at its discretion, terminate this Agreement in accordance with Section 11.5.

8.8 Patent Oppositions and Other Proceedings.

(a) **Third-Party Patent Rights.** If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non- infringement, reexamination or other attack upon the validity, title or enforceability of a Patent Controlled by a Third Party and having one or more claims that covers a Product, or the use, sale, offer for sale or importation of a Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 8.7, in which case the provisions of Section 8.7 shall govern), such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Harrow shall have the first right, but not the obligation, to bring at its own expense and in its sole control such action in the Territory. If Harrow does not bring such an action in the Territory, [***] of notification thereof pursuant to this Section 8.8(a) (or earlier, if required by the nature of the proceeding), then Wakamoto shall have the right, but not the obligation, to bring, at Wakamoto's sole expense, such action. The Party not bringing an action under this Section 8.8(a) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to reimburse each Party's expenses in such action, and any remaining amounts shall be retained by the Party who brings such action.

(b) **Parties' Patent Rights.** If any Wakamoto Patent or Joint Patent becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 8.6, in which case the provisions of Section 8.6 shall govern), then the Party responsible for filing, preparing, prosecuting and maintaining such Patent as set forth in Section 8.3 hereof, shall control such defense at its own expense. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under Applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If either Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third-Party action at its own expense. Any awards or amounts received in bringing any such action shall be first allocated to reimburse each Party's expenses in such action, and any remaining amounts shall be retained by the controlling Party.

**ARTICLE 9.
REPRESENTATIONS, WARRANTIES AND COVENANTS**

Articles 9 and 27 of the Supply Agreement sets forth and shall govern the representations, warranties and covenants of the Parties under this Agreement.

**ARTICLE 10.
CONFIDENTIALITY**

Article 11 of the Supply Agreement sets forth and shall govern the confidentiality obligations under this Agreement.

**ARTICLE 11.
TERM AND TERMINATION**

Articles 15, 16 and 17 of the Supply Agreement sets forth and shall govern the Term and Termination of this Agreement.

In the event of termination of this Agreement, in addition to the provisions of this Agreement that continue in effect in accordance with their terms, the following provisions of this Agreement shall survive: Articles 1, 7 (but only to the extent relating to milestone events occurring on or prior to the date of termination or for sales of Product), 9, 10, 11, 12, 13 (solely as to activities arising during the Term or as to any activities conducted in the course of a Party's exercise of a license surviving the Term), and 14 and Sections 2.2, 3.6, 4.2, 5.2, (with respect to any royalty obligations that arise on or prior to termination), 6.2, 7.4, 8.1, 8.2 (with respect to any disclosure obligations that arise on or prior to termination), 8.3(c), 8.3(d)(ii), 8.3(d)(iii) and 8.6(d) (to the extent any suit or action under that section is still pending upon termination).

**ARTICLE 12.
DISPUTE RESOLUTION**

Article 20 of the Supply Agreement sets forth and shall govern the Dispute Resolution Mechanism under this Agreement.

Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent or trademark relating to a Product that is the subject of this Agreement shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent or trademark laws of the country in which such Patent or trademark rights were granted or arose.

**ARTICLE 13.
INDEMNIFICATION**

Article 9 of the Supply Agreement sets forth and shall govern the Indemnification and Insurance provisions under this Agreement. Article 14 of the Supply Agreement sets forth and shall govern the Limitation of Liability provisions under this Agreement.

ARTICLE 14.
MISCELLANEOUS

Articles 21-26 and 28-31 of the Supply Agreement sets forth and shall govern the miscellaneous provisions under this Agreement.

This Agreement and the Supply Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and shall supersede any previous understandings or agreements relating thereto. This Agreement may be amended only by a written instrument duly signed by the authorized representative of each party hereto.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their duly authorized representatives as of the date first written above.

HARROW HEALTH, INC.

By: /s/ Mark L. Baum

Name: Mark L. Baum

Title: CEO

WAKAMOTO PHARMACEUTICAL CO., LTD.

By: /s/ Norihisa Kojima

Name: Norihisa Kojima

Title: President & CEO

Annex 1

Estimated Sales Forecast of Triamcinolone Acetonide, MAQAID, ophthalmic injection 40 mg

	1 st year	2 nd year	3 rd year	4 th year	5 th year
Number of the Product (Vials)	[***]	[***]	[***]	[***]	[***]

**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, 2021

/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, 2021

/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, 2021 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, 2021

/s/ Mark L. Baum

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

Date: November 9, 2021

/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.
