

**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, 2022

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 11, 2022, there were 27,413,654 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

	September 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	\$ 44,959,000	\$ 42,167,000
Investment in Eton Pharmaceuticals	4,162,000	8,503,000
Accounts receivable, net	6,743,000	4,470,000
Inventories	5,283,000	4,217,000
Prepaid expenses and other current assets	2,927,000	1,305,000
Total current assets	64,074,000	60,662,000
Property, plant and equipment, net	3,291,000	3,141,000
Capitalized software costs, net	1,878,000	1,313,000
Operating lease right-of-use assets	7,688,000	5,935,000
Intangible assets, net	19,632,000	15,813,000
Investment in Melt Pharmaceuticals	2,097,000	11,133,000
Goodwill	332,000	332,000
TOTAL ASSETS	\$ 98,992,000	\$ 98,329,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 14,112,000	\$ 6,337,000
Accrued payroll and related liabilities	3,441,000	3,089,000
Deferred revenue and customer deposits	115,000	16,000
Current portion of operating lease obligations	703,000	272,000
Current portion of finance lease obligations	-	8,000
Total current liabilities	18,371,000	9,722,000
Operating lease obligations, net of current portion	7,520,000	6,012,000
Finance lease obligations, net of current portion	-	10,000
Loans payable, net of current portion and unamortized debt discount	72,239,000	71,654,000
TOTAL LIABILITIES	98,130,000	87,398,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock, \$0.001 par value, 50,000,000 shares authorized, 27,074,307 and 26,902,763 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	27,000	27,000
Additional paid-in capital	111,738,000	106,666,000
Accumulated deficit	(110,548,000)	(95,407,000)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY	1,217,000	11,286,000
Noncontrolling interests	(355,000)	(355,000)
TOTAL STOCKHOLDERS' EQUITY	862,000	10,931,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 98,992,000	\$ 98,329,000

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

HARROW HEALTH, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product sales, net	\$ 21,575,000	\$ 17,811,000	\$ 63,433,000	\$ 50,056,000
Other revenues	1,248,000	900,000	4,833,000	2,232,000
Total revenues	<u>22,823,000</u>	<u>18,711,000</u>	<u>68,266,000</u>	<u>52,288,000</u>
Cost of sales	(6,721,000)	(4,947,000)	(19,218,000)	(13,134,000)
Gross profit	<u>16,102,000</u>	<u>13,764,000</u>	<u>49,048,000</u>	<u>39,154,000</u>
Operating expenses:				
Selling, general and administrative	15,421,000	11,356,000	43,004,000	28,643,000
Research and development	775,000	6,125,000	2,347,000	7,142,000
Total operating expenses	<u>16,196,000</u>	<u>17,481,000</u>	<u>45,351,000</u>	<u>35,785,000</u>
(Loss) income from operations	<u>(94,000)</u>	<u>(3,717,000)</u>	<u>3,697,000</u>	<u>3,369,000</u>
Other (expense) income:				
Interest expense, net	(1,800,000)	(1,685,000)	(5,386,000)	(3,512,000)
Equity in losses of unconsolidated entities	(3,504,000)	(706,000)	(9,036,000)	(2,967,000)
Investment loss from Eton Pharmaceuticals	(1,031,000)	(2,220,000)	(4,341,000)	(8,639,000)
Loss on early extinguishment of debt	-	-	-	(756,000)
Gain on forgiveness of PPP loan	-	-	-	1,967,000
Other expense, net	-	-	-	(51,000)
Total other expense, net	<u>(6,335,000)</u>	<u>(4,611,000)</u>	<u>(18,763,000)</u>	<u>(13,958,000)</u>
Loss before income taxes	<u>(6,429,000)</u>	<u>(8,328,000)</u>	<u>(15,066,000)</u>	<u>(10,589,000)</u>
Income taxes	(35,000)	-	(75,000)	-
Net loss	<u>(6,464,000)</u>	<u>(8,328,000)</u>	<u>(15,141,000)</u>	<u>(10,589,000)</u>
Preferred dividends and accretion of preferred stock issuance costs	-	-	-	(472,000)
Net loss attributable to common stockholders	<u>\$ (6,464,000)</u>	<u>\$ (8,328,000)</u>	<u>\$ (15,141,000)</u>	<u>\$ (11,061,000)</u>
Basic and diluted net loss per share of common stock	<u>\$ (0.24)</u>	<u>\$ (0.31)</u>	<u>\$ (0.55)</u>	<u>\$ (0.42)</u>
Weighted average number of shares of common stock outstanding, basic and diluted	<u>27,349,642</u>	<u>27,112,531</u>	<u>27,293,756</u>	<u>26,626,722</u>

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

HARROW HEALTH, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Three and Nine Months Ended September 30, 2022 and 2021

	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, 2020	-	\$ -	25,749,875	\$ 26,000	\$ 104,557,000	\$ (77,400,000)	\$ 27,183,000	(355,000)	\$ 26,828,000
Issuance of common stock in connection with:									
Exercise of warrants	-	-	311,369	-	-	-	-	-	-
Exercise of employee stock-based options	-	-	25,480	-	65,000	-	65,000	-	65,000
Vesting of RSUs	-	-	1,207,500	1,000	(1,000)	-	-	-	-
Shares withheld related to net share settlement of equity awards	-	-	(391,461)	-	(3,228,000)	-	(3,228,000)	-	(3,228,000)
Issuance of preferred shares, net of discount and issuance costs	440,000	-	-	-	10,655,000	-	10,655,000	-	10,655,000
Redemption of preferred shares	(440,000)	-	-	-	(11,000,000)	-	(11,000,000)	-	(11,000,000)
Payment of preferred dividends	-	-	-	-	(127,000)	-	(127,000)	-	(127,000)
Stock-based compensation expense	-	-	-	-	3,630,000	-	3,630,000	-	3,630,000
Net loss	-	-	-	-	-	(10,589,000)	(10,589,000)	-	(10,589,000)
Balance at September 30, 2021	-	\$ -	26,902,763	\$ 27,000	\$ 104,551,000	\$ (87,989,000)	\$ 16,589,000	\$ (355,000)	\$ 16,234,000
Balance at December 31, 2021	-	\$ -	26,902,763	\$ 27,000	\$ 106,666,000	\$ (95,407,000)	\$ 11,286,000	\$ (355,000)	\$ 10,931,000
Issuance of common stock in connection with:									
Exercise of consultant stock-based options	-	-	4,054	-	-	-	-	-	-
Exercise of employee stock-based options	-	-	92,261	-	7,000	-	7,000	-	7,000
Vesting of RSUs	-	-	185,000	1,000	(1,000)	-	-	-	-
Shares withheld related to net share settlement of equity awards	-	-	(109,771)	(1,000)	(875,000)	-	(876,000)	-	(876,000)
Stock-based compensation expense	-	-	-	-	5,941,000	-	5,941,000	-	5,941,000
Net loss	-	-	-	-	-	(15,141,000)	(15,141,000)	-	(15,141,000)
Balance at September 30, 2022	-	\$ -	27,074,307	\$ 27,000	\$ 111,738,000	\$ (110,548,000)	\$ 1,217,000	\$ (355,000)	\$ 862,000
Balance at June 30, 2021	-	\$ -	26,893,896	\$ 27,000	\$ 102,837,000	\$ (79,661,000)	\$ 23,203,000	\$ (355,000)	\$ 22,848,000
Issuance of common stock in connection with:									
Exercise of employee stock-based options	-	-	8,867	-	17,000	-	17,000	-	17,000
Stock-based compensation expense	-	-	-	-	1,697,000	-	1,697,000	-	1,697,000
Net loss	-	-	-	-	-	(8,328,000)	(8,328,000)	-	(8,328,000)
Balance at September 30, 2021	-	\$ -	26,902,763	\$ 27,000	\$ 104,551,000	\$ (87,989,000)	\$ 16,589,000	\$ (355,000)	\$ 16,234,000
Balance at June 30, 2022	-	\$ -	27,069,978	\$ 27,000	\$ 109,806,000	\$ (104,084,000)	\$ 5,749,000	\$ (355,000)	\$ 5,394,000
Issuance of common stock in connection with:									
Exercise of consultant stock-based options	-	-	4,054	-	-	-	-	-	-
Exercise of employee stock-based options	-	-	275	-	-	-	-	-	-

stock-based options

Stock-based compensation expense	-	-	-	-	1,932,000	-	1,932,000	-	1,932,000
Net loss	-	-	-	-	-	(6,464,000)	(6,464,000)	-	(6,464,000)
Balance at September 30, 2022	-	\$ -	27,074,307	\$ 27,000	\$ 111,738,000	\$ (110,548,000)	\$ 1,217,000	\$ (355,000)	\$ 862,000

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

HARROW HEALTH, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Nine Months Ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (15,141,000)	\$ (10,589,000)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization of property, plant and equipment	1,090,000	1,275,000
Amortization of intangible assets	1,200,000	122,000
Amortization of operating lease right-of-use assets	435,000	422,000
Provision for bad debt expense	36,000	36,000
Amortization of debt issuance costs and discount	585,000	480,000
Gain on forgiveness of PPP loan	-	(1,967,000)
Investment loss from investment in Eton	4,341,000	8,639,000
Equity in losses of unconsolidated entities	9,036,000	2,967,000
Interest paid-in-kind from note receivable	-	(136,000)
Loss on early extinguishment of loan	-	706,000
Stock-based compensation	5,941,000	3,630,000
Changes in assets and liabilities:		
Accounts receivable	(2,309,000)	(1,532,000)
Inventories	(1,066,000)	37,000
Prepaid expenses and other current assets	(716,000)	(866,000)
Accounts payable and accrued expenses	1,534,000	2,983,000
Accrued payroll and related liabilities	352,000	428,000
Deferred revenue and customer deposits	99,000	(63,000)
NET CASH PROVIDED BY OPERATING ACTIVITIES	5,417,000	6,572,000
CASH FLOWS FROM INVESTING ACTIVITIES		
Net proceeds on sale of investments	-	9,827,000
Investment in patent and trademark assets	(19,000)	(75,000)
Issuance of note receivable, Melt Pharmaceuticals	-	(12,592,000)
Purchases of property, plant and equipment	(1,719,000)	(1,649,000)
NET CASH USED IN INVESTING ACTIVITIES	(1,738,000)	(4,489,000)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on finance lease obligations	(18,000)	(5,000)
Net proceeds from 8.625% notes payable, net of costs	-	71,073,000
Principal and exit fee payments on SWK loan	-	(15,961,000)
Payment of taxes upon vesting of RSUs	(876,000)	(3,228,000)
Proceeds from exercise of stock options	7,000	65,000
Sale of preferred stock, net of discount and issuance costs	-	10,655,000
Redemption of preferred stock	-	(11,000,000)
Payment of preferred stock dividends	-	(127,000)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(887,000)	51,472,000
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	2,792,000	53,555,000
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	42,167,000	4,301,000
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	\$ 44,959,000	\$ 57,856,000
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	\$ 44,959,000	\$ 57,656,000
Restricted cash	-	200,000
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	\$ 44,959,000	\$ 57,856,000
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	\$ 75,000	\$ -
Cash paid for interest	\$ 4,851,000	\$ 2,603,000
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of common stock upon vesting of RSUs	\$ -	\$ 1,000
Purchase of intangible asset included in accounts payable and accrued expenses	\$ 5,000,000	\$ -
Purchase of property, plant and equipment included in accounts payable and accrued expenses	\$ 86,000	\$ -
Insurance premium financed	\$ 906,000	\$ -
Right-of-use assets obtained in exchange for new operating lease obligations	\$ 2,188,000	\$ 1,753,000
Melt accounts receivable to note receivable	\$ -	\$ 908,000

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

HARROW HEALTH, INC.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the Three and Nine months ended September, 2022 and 2021

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 eyecare pharmaceutical company exclusively focused on the discovery, development, and commercialization of innovative ophthalmic therapies that are accessible and affordable.

The Company owns non-controlling equity positions in Surface Ophthalmics, Inc. (“Surface”) and Melt Pharmaceuticals, Inc. (“Melt”), both companies that began as subsidiaries of Harrow. 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, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022 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, 2021.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned and majority-owned subsidiaries.

Harrow consolidates entities in which it has a controlling financial interest. The Company assesses control under the variable interest entity (“VIE”) model to determine whether the Company is the primary beneficiary of that entity’s operations. The Company consolidates (i) entities in which it holds and/or controls, directly or indirectly, more than 50% of the voting rights, and (ii) entities that the Company deems to be a VIE. All intercompany accounts and transactions have been eliminated in consolidation.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following represents an update for the three and nine months ended September 30, 2022 to the significant accounting policies described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021.

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

As a result of shifts in the Company’s strategic plans to further focus on growing the Company’s ImprimisRx business and suspension of activities related to starting up development-stage pharmaceutical companies, along with changes to the Company’s organizational and internal reporting structure, beginning in January 2022, management no longer evaluates the Company’s business in two segments and instead focuses on the performance of the business as a single operating business.

Basic and Diluted Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as stock options, restricted stock units (“RSUs”) and warrants, outstanding during the period. Common equivalent shares (using the treasury stock method) from stock options, unvested RSUs and warrants were 5,622,997 and 5,657,046 at September 30, 2022 and 2021, respectively. Included in the basic and diluted net loss per share calculation were RSUs awarded to directors that had vested, but the issuance and delivery of the shares are deferred until the director resigns. The number of shares underlying vested RSUs at September 30, 2022 and 2021 was 303,454 and 258,117, respectively.

The following table shows the computation of basic net loss per share of common stock for the three and nine months ended September 30, 2022 and 2021:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator – net loss attributable to common stockholders	\$ (6,464,000)	\$ (8,328,000)	\$ (15,141,000)	\$ (10,589,000)
Denominator – weighted average number of shares outstanding, basic and diluted	27,349,642	27,112,531	27,293,756	26,626,722
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.31)	\$ (0.55)	\$ (0.42)

Investment in Eton Pharmaceuticals, Inc.

As of September 30, 2022, the Company owned 1,982,000 shares of Eton common stock, which represents less than 10% of the equity interests of Eton. At September 30, 2022, the fair market value of Eton’s common stock was \$2.10 per share. In accordance with the Accounting Standards Update (“ASU”) 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, the Company recorded an unrealized investment loss from its Eton common stock position of \$1,031,000 and \$4,341,000, and \$2,220,000 and \$8,639,000 during the three and nine months ended September 30, 2022 and 2021, respectively, related to the change in fair market value of its investment in Eton during the measurement period. As of September 30, 2022, the fair market value of the Company’s investment in Eton was \$4,162,000.

Investment in Melt Pharmaceuticals, Inc. – Related Party

The Company owns 3,500,000 shares of common stock of Melt (representing approximately 46% of the equity interests as of September 30, 2022). The Company analyzes its investment in Melt and related agreements on a regular basis to evaluate its position of variable interests in Melt. The Company has determined that it does not have the ability to control Melt, however it has the ability to exercise significant influence over the operating and financial decisions of Melt and uses the equity method of accounting for this investment. 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. Any intra-entity profits and losses are eliminated. During the year ended December 31, 2021, the Company reduced the carrying value of its common stock investment in Melt to \$0 as a result of the Company recording its share of equity losses in Melt since its deconsolidation in 2019. As of September 30, 2022 and at the time of entering into the Melt Loan Agreement (see Note 4), the Company owned 100% of Melt’s indebtedness. Following the reduction of the carrying value of the Company’s common stock investment in Melt to \$0, the Company began recording 100% of the equity method losses of Melt, based on its ownership of Melt’s total indebtedness. In addition, the Company treats interest paid in kind on the Melt Loan Agreement as an in-substance capital contribution and reduces its investment in Melt accordingly, rather than recording interest income. The Company has no other requirements to advance funds to Melt.

The following table summarizes the Company's investments in Melt as of September 30, 2022:

	Cost Basis	Share of Equity Method Losses	Paid-in-Kind Interest	In-substance Capital Contributions	Net Carrying value
Common stock	\$ 5,810,000	\$ (5,810,000)	\$ -	\$ -	\$ -
Loan	13,500,000	(11,403,000)	1,995,000	(1,995,000)	2,097,000
	<u>\$ 19,310,000</u>	<u>\$ (17,213,000)</u>	<u>\$ 1,995,000</u>	<u>\$ (1,995,000)</u>	<u>\$ 2,097,000</u>

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 of Surface (representing approximately 20% of Surface's equity interests following the closing of a round of financing completed by Surface in July 2021) 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 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. During the year ended December 31, 2021, the Company reduced its common stock investment in Surface to \$0 as a result of the Company recording its share of equity losses of Surface. The Company has no other investments in Surface.

The following table summarizes the Company's investment in Surface as of September 30, 2022:

	Cost Basis	Share of Equity Method Losses	Net Carrying value
Common stock	\$ 5,320,000	\$ (5,320,000)	\$ -

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, 2022 and December 31, 2021, no indicators of impairment existed.

NOTE 3. REVENUES

The Company accounts for contracts with customers in accordance with Accounting Standards Codification ("ASC") 606, *Revenues from Contracts with Customers*. The Company has three primary streams of revenue: (1) revenue recognized from sales of products through its pharmacy and outsourcing facility and sales of branded products to wholesalers through a third-party logistics ("3PL") partner, (2) revenue recognized from a commission agreement with a third party, and (3) revenue recognized from intellectual property licenses and asset purchase agreements.

Product Revenues

The Company sells prescription medications directly through its pharmacy, outsourcing facility and 3PL partner. Revenue from the Company's pharmacy services includes: (i) the portion of the price the client pays directly to the Company, net of any volume-related or other discounts paid back to the client, (ii) the price paid to the Company 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, the Company has identified the following:

1. *Identify the contract(s) with a customer:* A contract is deemed to exist when the customer places an order through receipt of a prescription, via an online order or via receipt of a purchase order from a customer. For branded products, orders are received through the Company's 3PL partner, and the customer takes title of the products via formal purchase orders placed and fulfilled.

2. *Identify the performance obligations in the contract:* Obligations for fulfillment of the Company's contracts consist of delivering the product to customers at their specified destination. ASU 2016-10 was issued in April 2016 and amended ASC 606 for shipping and handling activities as follows: If the customer takes control of the goods after shipment, shipping and handling activities would always be considered a fulfillment activity and not treated as a separate performance obligation. If the customer takes control of the goods before shipment, entities must make an accounting policy election to treat shipping and handling activities as either a fulfillment cost or as a separate performance obligation. The Company has elected to treat its shipping and handling activities as a fulfillment cost.
3. *Determine the transaction price:* The transaction price is based on an amount that reflects the consideration to which the Company expects to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and an estimate for returns and replacements established at the time of sale. The Company utilizes the services of a third-party professional services firm to estimate rebates and chargebacks associated with sales of its branded products. The transfer of promised goods is satisfied within a year, and therefore there are no significant financing components. There is no non-cash consideration related to product sales.
4. *Allocate the transaction price to the performance obligations in the contract:* Given that there is only one performance obligation for product sales, no allocation is necessary.
5. *Recognize revenue when (or as) the entity satisfies a performance obligation:* Revenue from products is recognized upon transfer of control of a product to a customer. This generally occurs upon shipment unless contractual terms with a customer state that transfer of control occurs at delivery.

Commission Revenues

The Company has entered into an agreement whereby it is paid a fee calculated based on sales the Company generates from a pharmaceutical product that is owned by a third party. The revenue earned from this arrangement is recognized, at which point there is no future performance obligation required by the Company and no consequential continuing involvement on the Company's part to recognize the associated revenue.

Revenues From Transfer of Acquired Product Profit

The Company entered into an agreement whereby it purchased the exclusive commercial rights to assets associated with certain ophthalmic products from another pharmaceutical company (the "Seller"). During a temporary, six month transition period, the Seller continued to manufacture and market these products and transfer the net profit from the sale of the products to the Company. The revenue recognized by the Company from the transfer of net profit was recognized at the time profit from the product sales were calculated by the Seller and confirmed by the Company, typically on a monthly basis, at which point there is no future performance obligation required by the Company and no consequential continuing involvement on the Company's part to recognize the associated revenue. On a quarterly basis, the Seller invoiced the Company for all credits and reimbursements ("Chargebacks") made to customers related to the products. The Company used historical actual experience to estimate Chargebacks associated with the net profit transferred. The estimate is recorded as a reduction in revenues in the Company's condensed consolidated statements of operations and accounts receivable in the condensed consolidated balance sheets at the time the revenue is recognized.

Intellectual Property License Revenues

The Company currently holds five intellectual property licenses and related agreements pursuant to which the Company has agreed to license or sell to 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 that 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, 2022 and 2021 consists of the following:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Product sales, net	\$ 21,575,000	\$ 17,811,000	\$ 63,433,000	\$ 50,056,000
Commission revenues	1,044,000	900,000	3,576,000	2,212,000
Transfer of profits	204,000	-	1,257,000	-
License revenues	-	10,000	-	20,000
Total revenues	<u>\$ 22,823,000</u>	<u>\$ 18,711,000</u>	<u>\$ 68,266,000</u>	<u>\$ 52,288,000</u>

Deferred revenue and customer deposits at September 30, 2022 and December 31, 2021 were \$115,000 and \$16,000, respectively. All deferred revenue and customer deposit amounts at December 31, 2021 were recognized as revenue during the nine months ended September 30, 2022.

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 February 2019, the Company and Melt entered into a Management Service Agreement between the Company and Melt (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 \$10,000. During the three and nine months ended September 30, 2022, the Company recorded \$30,000 and \$100,000, respectively, due from Melt for reimbursable expenses and amounts payable pursuant to the Melt MSA, which are included in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheets. As of September 30, 2022 and December 31, 2021, the Company was due \$139,000 and \$48,000, 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, 2022.

The Company’s Chief Executive Officer, Mark L. Baum, was previously a member of the Melt board of directors until his resignation during the year ended December 31, 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,	
	2022	2021
Revenues, net	\$ -	\$ -
Loss from operations	(9,064,000)	(3,765,000)
Net loss	<u>\$ (10,562,000)</u>	<u>\$ (3,907,000)</u>

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

	At September 30, 2022	At December 31, 2021
Current assets	\$ 3,638,000	\$ 11,278,000
Non-current assets	994,000	-
Total assets	\$ 4,632,000	\$ 11,278,000
Total liabilities	\$ 19,207,000	\$ 15,732,000
Total preferred stock and stockholders' deficit	(14,575,000)	(4,454,000)
Total liabilities and stockholders' equity	\$ 4,632,000	\$ 11,278,000

Melt Note Receivable

On September 1, 2021, the Company 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 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 were previously due and payable on September 1, 2022. In April 2022, the Company entered into a First Amendment and in September 2022, a Second Amendment (together, the "Amendments") to the Melt Loan Agreement. The Amendments (i) extended the maturity date of the Melt Loan Agreement to June 1, 2023, which can be extended further to September 1, 2026 upon Melt completing a qualifying financing of a minimum amount of \$10,000,000 from third-party investors, (ii) added conditions related to minimum cash amounts following a qualifying financing, and (iii) clarified the definition of material adverse effects. 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 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 \$908,000 owed to the Company for reimbursable expenses and amounts due under the Melt MSA prior to the effective date of the note receivable. As of September 30, 2022 and December 31, 2021, \$15,495,000 and \$14,076,000, respectively, in principal balance of the Melt Loan Agreement is payable to the Company.

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, 2022, the Company owned 3,500,000 shares of Surface common stock. Company directors Richard L. Lindstrom, Perry J. Sternberg and Mark L. Baum, who is also the Company's Chief Executive Officer, are directors of Surface. Dr. Lindstrom is a principal of Flying L Partners, an affiliate of an investor who purchased Surface Series A Preferred Stock.

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

	For the Nine Months Ended September 30,	
	2022	2021
Revenues, net	\$ -	\$ -
Loss from operations	(5,338,000)	(6,859,000)
Net loss	<u>\$ (5,338,000)</u>	<u>\$ (6,859,000)</u>

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

	At September 30, 2022	At December 31, 2021
	Current assets	\$ 16,625,000
Non-current assets	661,000	412,000
Total assets	<u>\$ 17,286,000</u>	<u>\$ 22,143,000</u>
Total liabilities	\$ 1,745,000	\$ 1,514,000
Total preferred stock and stockholders' deficit	15,541,000	20,629,000
Total liabilities and stockholders' equity	<u>\$ 17,286,000</u>	<u>\$ 22,143,000</u>

NOTE 6. INVENTORIES

Inventories are comprised of finished compounded formulations, over-the-counter and prescription retail pharmacy products, branded commercial pharmaceutical products, including those held at the Company's 3PL partner, related laboratory supplies and active pharmaceutical ingredients. The composition of inventories as of September 30, 2022 and December 31, 2021 was as follows:

	September 30, 2022	December 31, 2021
Raw materials	\$ 3,507,000	\$ 2,441,000
Work in progress	26,000	-
Finished goods	1,750,000	1,776,000
Total inventories	<u>\$ 5,283,000</u>	<u>\$ 4,217,000</u>

NOTE 7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at September 30, 2022 and December 31, 2021 consisted of the following:

	September 30, 2022	December 31, 2021
Prepaid insurance	\$ 1,165,000	\$ 728,000
Prepaid computer software licenses and related expenses	781,000	248,000
Due from Melt Pharmaceuticals	139,000	48,000
Other prepaid expenses	769,000	189,000
Deposits and other current assets	73,000	92,000
Total prepaid expenses and other current assets	<u>\$ 2,927,000</u>	<u>\$ 1,305,000</u>

NOTE 8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at September 30, 2022 and December 31, 2021 consisted of the following:

	September 30, 2022	December 31, 2021
Property, plant and equipment, net:		
Computer hardware	\$ 875,000	\$ 772,000
Furniture and equipment	843,000	443,000
Lab and pharmacy equipment	4,160,000	4,056,000
Leasehold improvements	6,276,000	5,703,000
	<u>12,154,000</u>	<u>10,974,000</u>
Accumulated depreciation	(8,863,000)	(7,833,000)
	<u>\$ 3,291,000</u>	<u>\$ 3,141,000</u>

For the three and nine months ended September 30, 2022, depreciation related to the property, plant and equipment was \$171,000 and \$928,000, respectively, compared to \$410,000 and \$1,202,000 during the same periods in 2021, respectively.

NOTE 9. CAPITALIZED SOFTWARE DEVELOPMENT COSTS

Capitalized software development costs at September 30, 2022 and December 31, 2021 consisted of the following:

	September 30, 2022	December 31, 2021
Capitalized internal-use software development costs	\$ 1,533,000	\$ 417,000
Acquired third-party software license for internal-use	159,000	684,000
Total gross capitalized software for internal-use	<u>1,692,000</u>	<u>1,101,000</u>
Accumulated amortization	(731,000)	(569,000)
Capitalized internal-use software in process	917,000	781,000
	<u>\$ 1,878,000</u>	<u>\$ 1,313,000</u>

The Company recorded amortization expense of \$76,000 and \$162,000 related to capitalized software development costs during the three and nine months ended September 30, 2022, respectively, and \$22,000 and \$73,000 during the same periods in 2021, respectively.

NOTE 10. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at September 30, 2022 consisted of the following:

	Amortization Periods (in years)	Cost	Accumulated Amortization	Impairment	Net Carrying Value
Patents	17-19	\$ 981,000	\$ (140,000)	\$ -	\$ 841,000
Licenses	20	100,000	(20,000)	-	80,000
Trademarks	Indefinite	264,000	-	-	264,000
Acquired NDAs	10	18,635,000	(1,023,000)	-	17,612,000
Customer relationships	3-15	1,519,000	(685,000)	-	834,000
Trade name	5	5,000	(5,000)	-	-
Non-competition clause	3-4	50,000	(50,000)	-	-
State pharmacy licenses	25	8,000	(7,000)	-	1,000
		<u>\$ 21,562,000</u>	<u>\$ (1,930,000)</u>	<u>\$ -</u>	<u>\$ 19,632,000</u>

Amortization expense for intangible assets for the three and nine months ended September 30, 2022 and 2021 was as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Patents	\$ 22,000	\$ 8,000	\$ 65,000	\$ 20,000
Licenses	2,000	1,000	13,000	2,000
Acquired NDAs	341,000	-	1,023,000	-
Customer relationships	33,000	34,000	99,000	100,000
	<u>\$ 398,000</u>	<u>\$ 43,000</u>	<u>\$ 1,200,000</u>	<u>\$ 122,000</u>

Estimated future amortization expense for the Company's intangible assets at September 30, 2022 is as follows:

Remainder of 2022	\$ 523,000
2023	2,092,000
2024	2,092,000
2025	2,092,000
2026	2,096,000
Thereafter	10,473,000
	<u>\$ 19,368,000</u>

NOTE 11. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at September 30, 2022 and December 31, 2021 consisted of the following:

	September 30, 2022	December 31, 2021
Accounts payable	\$ 7,043,000	\$ 5,174,000
Accrued insurance premium	906,000	-
Accrued IHEEZO milestone payment	5,000,000	-
Other accrued expenses	49,000	49,000
Accrued interest	1,114,000	1,114,000
Total accounts payable and accrued expenses	<u>\$ 14,112,000</u>	<u>\$ 6,337,000</u>

The Company financed all insurance policies for the policy term of August 17, 2022 through August 16, 2023. The financing agreement has an interest rate of 4.13% per annum and requires eight monthly payments of \$114,000.

NOTE 12. DEBT

8.625% Senior Notes Due 2026

In April 2021, the Company closed an offering of \$50,000,000 aggregate principal amount of 8.625% senior notes due April 2026, and in May 2021 issued an additional \$5,000,000 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 \$51,909,000 after deducting underwriting discounts and commissions and expenses of \$3,091,000. In June 2021, in a further issuance of the April Notes, the Company sold an additional \$20,000,000 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 \$278,000 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 \$19,164,000 after deducting underwriting discounts and commissions and expenses of \$1,158,000 and a premium on note issuance of \$322,000. 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 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 \$1,814,000 and \$5,436,000 for the three and nine months ended September 30, 2022, respectively, and \$1,464,000 and \$2,930,000 during the three and nine months ended September 30, 2021, respectively, and included amortization of debt issuance costs and discount of \$197,000 and \$585,000 for three and nine months ended September 30, 2022, respectively, and \$197,000 and \$389,000 during the three and nine months ended September 30, 2021, respectively.

At September 30, 2022, future minimum payments under the Company's debt were as follows:

	Amount
Remainder of 2022	\$ 1,617,000
2023	6,469,000
2024	6,469,000
2025	6,469,000
2026	77,158,000
Total minimum payments	98,182,000
Less: amount representing interest payments	(23,182,000)
Notes payable, gross	75,000,000
Less: unamortized discount, net of premium	(2,761,000)
Notes payable, net of unamortized discount	\$ 72,239,000

NOTE 13. LEASES

The Company leases office and laboratory space under the 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 5,789 square feet of office space in Carlsbad, California, which commenced in January 2022 and will expire in July 2027.
- An operating lease for 35,326 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 lease was amended, effective July 2020, to extend the term of the original lease and add 1,400 of additional square footage to the lease, and amended again in May 2021 to extend the term of the lease to July 2027 and add 8,900 square feet of space.
- 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.
- An operating lease for 11,552 square feet of lab and office space in Nashville, Tennessee which commenced in June 2022 and expires in June 2027.

At September 30, 2022, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 6.62% and 10.99 years, respectively.

During the three and nine months ended September 30, 2022, cash paid for amounts included for the operating lease liabilities was \$249,000 and \$622,000, respectively, and \$250,000 and \$752,000 during the same periods in 2021, respectively. During the three and nine months ended September 30, 2022, the Company recorded operating lease expense of \$309,000 and \$809,000, respectively, which is included in selling, general and administrative expenses.

Future lease payments under operating leases as of September 30, 2022 were as follows:

	Operating Leases
Remainder of 2022	\$ 303,000
2023	1,231,000
2024	1,262,000
2025	1,093,000
2026	1,114,000
Thereafter	6,801,000
Total minimum lease payments	11,804,000
Less: amount representing interest payments	(3,581,000)
Total operating lease liabilities	8,223,000
Less: current portion, operating lease liabilities	(703,000)
Operating lease liabilities, net of current portion	\$ 7,520,000

During the nine months ended September 30, 2022, the Company repaid all remaining amounts owed under its finance lease and no future payments are due related to finance leases.

NOTE 14. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Preferred Stock

At September 30, 2022 and December 31, 2021, the Company had 5,000,000 shares of preferred stock, \$0.001 par value, authorized and no shares of preferred stock issued and outstanding.

Common Stock

During the nine months ended September 30, 2022, the Company issued 53,594 shares of common stock to Mark L. Baum, the Company's Chief Executive Officer, upon the cashless exercise of options to purchase 125,000 shares at an exercise price of \$2.40 per share. The Company withheld from Mr. Baum 36,014 shares as consideration for the cashless exercise and an additional 35,392 shares for payroll tax obligations totaling \$295,000.

During the nine months ended September 30, 2022, the Company issued 4,054 shares of common stock to consultants upon the cashless exercise of options to purchase 15,995 shares at an exercise price of \$7.07 per share. The Company withheld 11,941 shares as consideration for the cashless exercise.

During the nine months ended September 30, 2022, the Company issued 3,275 shares of common stock and received net proceeds of \$7,000 upon the exercise of options to purchase 3,275 shares of common stock with exercise prices between \$1.70 to \$3.95 per share.

During the nine months ended September 30, 2022, 50,000 RSUs granted in February 2019 to Andrew R. Boll, the Company's Chief Financial Officer, vested, and in February 2022, the Company issued 29,395 shares of common stock to Mr. Boll, net of 20,605 shares of common stock withheld for payroll tax withholdings totaling \$162,000.

During the nine months ended September 30, 2022, 50,000 RSUs granted in February 2019 to John P. Saharek, the President of ImprimisRx, vested, and in February 2022, the Company issued 24,077 shares of common stock to Mr. Saharek, net of 25,923 shares of common stock withheld for payroll tax withholdings totaling \$204,000.

During the nine months ended September 30, 2022, 35,000 RSUs granted in February 2019 vested, and in February 2022, the Company issued 20,298 shares of common stock, net of 14,702 shares of common stock withheld for payroll tax withholdings totaling \$116,000.

During the nine months ended September 30, 2022, 50,000 RSUs granted in May 2019 vested, and in May 2022, the Company issued 36,851 shares of common stock, net of 13,149 shares of common stock withheld for payroll tax withholdings totaling \$99,000.

During the nine months ended September 30, 2022, 35,693 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, 2022, the 2017 Plan provides for the issuance of a maximum of 6,000,000 shares of the Company's common stock. The purposes 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 2,058,280 shares available for future issuances under the 2017 Plan at September 30, 2022.

Stock Options

A summary of stock option activity under the Plans for the nine months ended September 30, 2022 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding – January 1, 2022	3,039,546	\$ 5.52		
Options granted	323,250	\$ 7.30		
Options exercised	(144,270)	\$ 2.92		
Options cancelled/forfeited	(47,500)	\$ 7.41		
Options outstanding – September 30, 2022	3,171,026	\$ 5.79	4.59	\$ 19,919,000
Options exercisable	2,462,904	\$ 5.33	4.19	\$ 16,609,000
Options vested and expected to vest	3,037,832	\$ 5.72	4.57	\$ 19,314,000

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, 2022, based on the closing price of the Company's common stock of \$12.07 on that date.

During the nine months ended September 30, 2022, the Company granted stock options to certain employees. 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 ten years. Vesting terms for options granted to employees during the three and nine months ended September 30, 2022 included the following vesting schedule: 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:

	2022
Weighted-average fair value of options granted	\$ 4.49
Expected terms (in years)	6.11
Expected volatility	68-70%
Risk-free interest rate	1.54-3.19%
Dividend yield	-

The following table summarizes information about stock options outstanding and exercisable at September 30, 2022:

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 - \$2.23	595,612	4.74	\$ 1.97	595,612	\$ 1.97	
\$2.40 - \$3.50	53,568	5.80	\$ 3.00	44,162	\$ 2.90	
\$3.95	370,000	3.50	\$ 3.95	370,000	\$ 3.95	
\$4.08 - \$6.30	578,850	4.61	\$ 5.76	540,006	\$ 5.82	
\$6.75 - \$7.30	413,000	7.91	\$ 7.18	237,250	\$ 7.29	
\$7.37 - \$7.79	287,323	5.97	\$ 7.54	140,073	\$ 7.47	
\$7.87	600,000	2.83	\$ 7.87	300,000	\$ 7.87	
\$7.89 - \$8.75	82,673	3.06	\$ 8.06	52,051	\$ 8.15	
\$8.98	10,000	8.34	\$ 8.98	3,750	\$ 8.98	
\$8.99	180,000	0.59	\$ 8.99	180,000	\$ 8.99	
\$1.47 - \$8.99	<u>3,171,026</u>	4.59	\$ 5.79	<u>2,462,904</u>	\$ 5.33	

As of September 30, 2022, there was approximately \$1,830,000 of total unrecognized compensation expense related to unvested stock options granted under the Plans. That expense is expected to be recognized over the weighted-average remaining vesting period of 4.34 years. The stock-based compensation for all stock options was \$241,000 and \$771,000 during the three and nine months ended September 30, 2022, respectively, and \$355,000 and \$1,376,000 during the same periods in 2021, respectively.

The intrinsic value of options exercised during the nine months ended September 30, 2022 was \$794,000.

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.

A summary of the Company's RSU activity (including performance stock units) and related information for the nine months ended September 30, 2022 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested – January 1, 2022	2,233,202	\$ 6.78
RSUs granted	65,615	\$ 7.62
RSUs vested	(220,693)	\$ 6.60
RSUs cancelled/forfeited	-	-
RSUs unvested – September 30, 2022	<u>2,078,124</u>	\$ 6.82

As of September 30, 2022, the total unrecognized compensation expense related to unvested RSUs was approximately \$5,755,000, which is expected to be recognized over a weighted-average period of 0.85 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, 2022 was \$1,691,000 and \$5,170,000, respectively, and \$1,340,000 and \$2,167,000 during the same periods in 2021, respectively.

Warrants

From time to time, the Company has issued 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, 2022 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted Average Exercise Price
Warrants outstanding – January 1, 2022	373,847	\$ 2.08
Granted	-	
Exercised	-	
Expired	-	
Warrants outstanding and exercisable – September 30, 2022	<u>373,847</u>	<u>\$ 2.08</u>
Weighted average remaining contractual life of the outstanding warrants in years – September 30, 2022	<u>1.8</u>	

Warrants outstanding and exercisable as of September 30, 2022 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 \$0 in stock-based compensation expense related to subsidiary stock options during the three and nine months ended September 30, 2022, and \$2,000 and \$87,000 during the same periods in 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,	
	2022	2021	2022	2021
Employees – selling, general and administrative	\$ 1,611,000	\$ 1,435,000	\$ 4,942,000	\$ 2,984,000
Employees – R&D	163,000	144,000	525,000	328,000
Directors – selling, general and administrative	125,000	118,000	337,000	318,000
Consultants – R&D	33,000	-	137,000	-
Total	<u>\$ 1,932,000</u>	<u>\$ 1,697,000</u>	<u>\$ 5,941,000</u>	<u>\$ 3,630,000</u>

NOTE 15. COMMITMENTS AND CONTINGENCIES

Legal

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.

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.

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% to 6% of net sales, dependent upon the final formulation of the Klarity Product sold. In addition, the Company was required to make certain milestone payments to Dr. Lindstrom. All of the above referenced milestone payments were payable at the Company's election in cash or shares of the Company's restricted common stock. Payments totaling \$77,000 and \$199,000 were made during the three and nine months ended September 30, 2022, respectively, compared to \$44,000 and \$114,000 during the same periods in 2021, respectively. Royalty expenses were \$67,000 and \$244,000 during the three and nine months ended September 30, 2022, respectively, compared to \$51,000 and \$130,000 during the same periods in 2021, respectively, and were included in accounts payable to Dr. Lindstrom.

Injectable Asset Purchase Agreement – Related Party

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

Under the terms of the Lindstrom APA, the Company is required to make royalty payments to Dr. Lindstrom ranging from 2% to 3% of net sales, dependent upon the final formulation and patent protection of the Lindstrom Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including an initial payment of \$33,000 upon execution of the Lindstrom APA. Dr. Lindstrom was paid \$8,000 and \$23,000 in cash during the three and nine months ended September 30, 2022, respectively, and \$7,000 and \$21,000 during the same periods in 2021, respectively. The Company incurred \$9,000 and \$24,000 for royalty expenses related to the Lindstrom APA during the three and nine months ended September 30, 2022, respectively, and \$7,000 and \$21,000 during the same periods in 2021, respectively.

Presbyopia Asset Purchase Agreement – Related Party

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

Under the terms of the Presbyopia APA, the Company is required to make royalty payments to Dr. Lindstrom ranging from 2% to 4% of net sales, dependent upon the final formulation and patent protection of the Presbyopia Product sold. Dr. Lindstrom was paid \$0 in cash during the three and nine month periods ended September 30, 2022 and 2021, and was due \$0 at September 30, 2022 and 2021. The Company incurred \$0 for royalty expenses related to the Presbyopia APA during the three and nine month periods ended September 30, 2022 and 2021.

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. During the three and nine months ended September 30, 2022, \$185,000 and \$695,000 were incurred under these agreements as royalty expenses, respectively, and \$285,000 and \$778,000 during the same periods in 2021, respectively.

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 (“IHEEZO”) in the U.S. and Canada.

Pursuant to the Sintetica Agreement, the Company agreed to pay Sintetica a per unit transfer price to supply IHEEZO, 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 (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 is responsible for regulatory filings for IHEEZO in the U.S. The Upfront Payment along with an additional milestone payment of \$3,117,000 was paid and recorded as R&D expenses during the year ended December 31, 2021. During the three and nine months ended September 30, 2022, \$5,000,000 was accrued under the Sintetica Agreement related to the FDA approval of the United States NDA for IHEEZO.

Subject to certain limitations, the Sintetica Agreement has a ten-year term, 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 agreed to supply MAQ-100 to the Company, and the Company agreed to 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 \$2,000,000 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, the Company is responsible for regulatory filings and fees for MAQ-100 in the U.S. and Canada. Through September 30, 2022, no amounts have been paid or accrued under the Wakamoto Agreements.

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

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 pays 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 agreed to use commercially reasonable efforts to promote and market DEXYCU in the U.S.

Pursuant to a mutual termination agreement entered into on October 7, 2022 the Dexycu Agreement will terminate on January 1, 2023 (see Note 17 for more information). During the three and nine months ended September 30, 2022, the Company recorded \$1,044,000 and \$3,576,000, respectively, and \$900,000 and \$2,212,000 during the same periods in 2021, 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% to 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 \$1,041,000 and \$3,188,000 were incurred under these agreements for commission expenses during the three and nine months ended September 30, 2022, respectively, and \$953,000 and \$2,766,000 during the same periods in 2021, respectively.

NOTE 16. CONCENTRATIONS

The Company has two products that each comprised more than 10% of total revenues during the three and nine month periods ended September 30 2022 and 2021, respectively. These products collectively accounted for 34% and 33% of revenues during the three and nine months ended September 30, 2022, respectively, and 35% and 36% during the same periods in 2021, respectively.

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 during the three and nine months ended September 30, 2022 and 2021.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 52% and 66% of active pharmaceutical ingredient purchases during the three and nine months ended September 30, 2022, respectively, and 59% and 71% during the same periods in 2021, respectively.

NOTE 17. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to September 30, 2022 through the filing date of this Quarterly Report. Based on its evaluation, no events other than those described below need to be disclosed.

In October 2022, the Company issued 306,347 shares of its common stock upon the cashless exercise of warrants to purchase 373,847 shares of common stock, with an exercise price \$2.08 per share.

In October 2022, the Company issued 31,000 shares of common stock upon the exercise of options to purchase 31,000 shares of common stock at exercise prices of \$1.70 - \$8.40 per share.

Eyepoint Termination

Following the preliminary Hospital Outpatient Prospective Payment System (HOPPS) rule proposed by the Centers for Medicare & Medicaid Services (CMS) in July of 2022, which did not contain an extension of the pass-through payment period for Dexycu beyond December 31, 2022, the Company entered into a Mutual Termination Agreement (the "Termination Agreement") with Eyepoint on October 7, 2022, pursuant to which Eyepoint and the Company agreed (a) that the Company will continue to support the sale of Dexycu through the fourth quarter of 2022, consistent with the Company's level of effort during the January through June 2022 period, (b) to decrease the required minimum quarterly sales levels based on Dexycu unit demand for the fourth quarter of 2022, and (c) to terminate the Dexycu Agreement, along with ancillary letter agreements, effective January 1, 2023.

Divestment of Non-Ophthalmology Revenues

In October 2022, wholly-owned subsidiaries of the Company ("Imprimis") entered into an Asset Purchase Agreement (the "RPC Agreement") with Innovation Compounding Pharmacy, LLC (the "Buyer"). The closing of the RPC Agreement was made effective on September 30, 2022; however, control of the assets transferred to the Buyer, and a closing payment was made, in October 2022. Under the terms of the RPC Agreement, Imprimis agreed to sell substantially all of its assets associated with its non-ophthalmology related compounding product line, including but not limited to, certain intellectual property rights, customer lists, databases, and formulations (the "RPC Assets"). The Buyer agreed to make offers of employment to six of the Company's employees that were responsible for the sales activities associated with the RPC Assets. In connection with the RPC Agreement, Imprimis entered into a separate transition services agreement with the Buyer related to providing on going services, such as procuring and dispensing prescription orders associated with RPC Assets. The Company expects Imprimis to provide transition services to the Buyer for up to six months following the effective date of the RPC Agreement. Under the terms of the RPC Agreement, the Buyer paid Imprimis an aggregate cash amount of \$6,000,000 in October 2022. In addition, the Buyer is obligated to pay up to \$4,500,000 to Imprimis based on mutually agreed upon revenue milestones during the calendar year 2023. The

Company determined that the disposal of the related net assets does not qualify for reporting as a discontinued operation because it does not represent a strategic shift that has or will have a major effect on the Company's operations and financial results.

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, 2021 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 ImprimisRx, LLC, ImprimisRx NJ, LLC dba ImprimisRx, Imprimis NJOF, LLC, and Harrow Eye, LLC. 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, including inflation and supply chain challenges; 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 eyecare pharmaceutical company exclusively focused on the discovery, development, and commercialization of innovative ophthalmic therapies that are accessible and affordable.

The Company owns non-controlling equity positions in Surface Ophthalmics, Inc. (“Surface”) and Melt Pharmaceuticals, Inc. (“Melt”), both companies that began as subsidiaries of Harrow. Harrow also owns royalty rights in various drug candidates being developed by Surface and Melt.

ImprimisRx

ImprimisRx is our ophthalmology-focused prescription pharmaceutical compounding business. From its inception in 2014, ImprimisRx, which consists of integrated research and development, production, dispensing/distribution, sales, marketing, and customer service capabilities, has offered physician customers and their patients access to critical medicines to meet their clinical needs. Initially, ImprimisRx focused exclusively on compounded medications to serve needs unmet by commercially available medications. We also make these unique formulations available at prices that are, in most cases, lower than non-customized commercial medications. ImprimisRx's customer base has grown to include more than 10,000 U.S. eyecare dedicated prescribers and institutions. 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 others are 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 (a) as patient-specific medications from our 503A pharmacy; or, (b) 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"). In August 2020, ImprimisRx entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted ImprimisRx the right to 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 the U.S. In October 2022, we entered into a mutual termination agreement with Eyepoint, pursuant to which we agreed to (a) continue to support the sale of DEXYCU through the fourth quarter of 2022, consistent with our level of effort during the January through June 2022 period, (b) decrease the required minimum quarterly sales levels based on DEXYCU unit demand for the fourth quarter of 2022, and (c) terminate the Dexycu Agreement, along with ancillary letter agreements, effective January 1, 2023. As a result, we expect our commissions from sales of DEXYCU to decrease through the end of 2022 and cease in 2023; however such effect is not expected to have a material impact on our business, financial statements and cash flows.

Branded Pharmaceuticals and Drug Candidates

Over the past two years, in order to more fully serve the needs of our growing customer base, we have invested in broadening our product portfolio to include FDA-approved products. Our investments in this regard have led to the pursuit and completion of several announced transactions, and others we are continuing to pursue, all of which are focused in eyecare pharmaceuticals. We believe that our continued investments in these and other products will result in our ability to provide more physician prescribers and their patients with access to a complete portfolio of affordable eyecare pharmaceuticals to address their clinical needs.

IOPIDINE®, MAXITROL®, MOXEZA®

In December 2021, we acquired U.S. commercial rights to four FDA-approved ophthalmic medicines: IOPIDINE 1% and 0.5% (apraclonidine hydrochloride); MAXITROL (neomycin/polymyxin B/dexamethasone) ophthalmic suspension; and MOXEZA (moxifloxacin hydrochloride). We believe by expanding our product portfolio to include branded FDA-approved products, we will be uniquely positioned to leverage our commercial platform to introduce unique lifecycle management strategies that could grow sales and address needs of our customers that we are unable to meet with our other compounded product offerings.

At the time of closing the acquisition of the four products, we agreed to a transitional period with the seller, which lasted nine months following the closing of the transaction. During the transition period, the seller continued to sell the products and transferred the net profit from those sales to us. Following the transition period which ended in June 2022, we made IOPIDINE 1% and MAXITROL commercially available, and expect to re-launch MOXEZA at a later date.

IHEEZO™

In July 2021, we acquired the exclusive marketing and supply rights to IHEEZO (chloroprocaine hydrochloride ophthalmic gel) 3% in the U.S. and Canada for ocular surface anesthesia from Sintetica S.A. ("Sintetica"). The FDA approved IHEEZO for ocular surface anesthesia in September 2022. IHEEZO is protected by an Orange Book listed patent that is valid until 2038. We expect to commercially launch IHEEZO in the U.S. market during 2023.

MAQ-100

In August 2021, we acquired the exclusive 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. In August 2022, we had a Type B meeting with the FDA to discuss our planned clinical program for MAQ-100. The FDA provided clarity on what would be required for a future NDA filing of MAQ-100, and we are working with Wakamoto accordingly in an effort to efficiently advance the clinical program of MAQ-100.

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

Carved-Out Businesses (De-Consolidated Businesses)

We have ownership interests in Surface, Melt, and Eton Pharmaceuticals, Inc. (“Eton”) and hold royalty interests in some of Surface’s and Melt’s drug candidates. These companies are pursuing market approval for their drug candidates under the Food Drug and Cosmetic Act, including in some instances under the abbreviated pathway described in Section 505(b)(2), which permits the submission of an 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.

Noncontrolling Equity Interests

Surface Ophthalmics, Inc.

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

- SURF-100 for Chronic Dry Eye Disease: Surface completed its 350-patient Phase 2 clinical trial, comparing five active arms of SURF-100 study drugs with the current market-leading prescription chronic dry eye treatments. According to Surface, the SURF-100 Phase 2 clinical trial achieved positive results for both signs and symptoms of chronic dry eye disease, as well as generating positive data on onset and duration of action.
- SURF-200 for Acute Dry Eye: Surface has completed enrollment of its Phase 2 clinical trial for SURF-200 and expects to announce top-line results later this year.
- SURF-201 for Pain and Inflammation Following Ocular Surgery: 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.

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 Surface’s equity and voting interests as of September 30, 2022. 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 began enrolling patients in its Phase 2 study for MELT-300 during the fourth quarter of 2021, and we expect Melt to release top-line data related to this study sometime during the fourth quarter of 2022.

In January 2019, Melt closed an offering of its Series A Preferred Stock. At that time, we gave up 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 Melt’s equity and voting interests issued and outstanding as of September 30, 2022. In September 2021, we provided Melt with a senior secured loan with a principal amount of \$13,500,000, which is intended to fund the Phase 2 program of MELT-300. In connection with the loan, we were given 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. In September 2022, Melt filed a registration statement on Form S-1 with the United States Securities and Exchange Commission related to an initial public offering of Melt’s common stock in an underwritten offering (the “Melt IPO”). The registration statement contains, among other things, a description of Melt’s business, financial statements and strategic plans. If the Melt IPO is completed, we expect to settle ten million dollars (\$10,000,000) of the principal balance of our loan to Melt in exchange for Melt common stock at the price of the Melt IPO, net of any underwriting discounts.

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 an innovative pharmaceutical company focused on developing, acquiring, and commercializing treatments for rare diseases. Eton currently commercializes ALKINDI SPRINKLE® and Carglumic Acid tablets and has four additional rare disease products under development, including dehydrated alcohol injection and the ZENEO® hydrocortisone autoinjector. In May 2017, we gave up our controlling interest in Eton. We own 1,982,000 shares of Eton common stock, which was less than 10% of the equity and voting interests issued and outstanding of Eton as of September 30, 2022.

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

We believe IHEEZO and possibly other drug candidates that we may develop will also be covered under Medicare Part B. New drugs approved by the FDA that are used in surgeries performed in a hospital outpatient departments or ambulatory surgical centers may receive a transitional pass-through reimbursement under Medicare, provided they meet certain criteria, including a “not insignificant” cost criterion. Pass-through status allows for separate payment (i.e., outside the packaged payment rate for the surgical procedure) under Medicare Part B, which consists of Medicare reimbursement for a drug based on a defined formula for calculating the minimum fee that a manufacturer may charge for the drug. Under current regulations of CMS, pass-through status applies for a period of three years; which is measured from the date Medicare makes its first pass-through payment for the product. Following the three-year period, the product would be incorporated into the cataract bundled payment system, which could significantly reduce the pricing for that product. We intend to apply for temporary pass-through reimbursement for IHEEZO during 2023. Following expiration of pass-through status, under current CMS policy, non-opioid pain management surgical drugs when used on Medicare Part B patients in an outpatient setting can qualify for ongoing separate payment. CMS’ current non-opioid separate payment policy, like other CMS policies, can be changed by CMS through its annual rulemaking and comment process. We believe that CMS will continue its separate payment policy for non-opioid pain management surgical drugs, which has been in effect since 2019.

In July of 2022, CMS issued its Proposed CY 2023 Payment Rule for Hospital Outpatient Services and ASCs. Based on the summary in the proposed rule, DEXYCU will no longer qualify as a separately payable product in an ASC or outpatient setting and will instead be bundled into the general cataract procedure code effective January 1, 2023, when the final rule, if approved as currently proposed, will go into effect.

Our proprietary ophthalmic compounded formulations are currently primarily available on a cash-pay basis. However, MOXEZA, MAXITROL and IOPIDINE are, and we expect that other drug candidates we are developing, if approved, will be eligible for reimbursement by third-party payors. We are devoting time and resources to seek reimbursement and patient pay opportunities for these and other drug products and candidates. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant challenges for products to be eligible for reimbursement 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 adverse 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 drug products and candidates 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 drug products and candidates, the market acceptance and opportunity for them 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 historical norms and trends as restrictions associated with elective procedures and the COVID-19 pandemic have eased.

However, given the unprecedented and dynamic nature of the COVID-19 pandemic, including any virus 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

Divestment of Non-Ophthalmic Revenues

In October 2022, we entered into an Asset Purchase Agreement (the “RPC Agreement”) with Innovation Compounding Pharmacy, LLC (the “Buyer”). The closing of the RPC Agreement was made effective on September 30, 2022. Under the terms of the RPC Agreement, the Company agreed to sell substantially all its assets associated with its non-ophthalmology related compounding business, including but not limited to, certain intellectual property rights, customer lists, databases, and formulations (the “RPC Assets”). The Buyer agreed to make offers of employment to six of the Company’s employees that were responsible for the sales activities associated with the RPC Assets. In connection with the RPC Agreement, the Company entered into a separate transition services agreement with the Buyer related to providing on going services, such as procuring and dispensing prescription orders associated with RPC Assets. The Company expects to provide transition services to the Buyer for up to six months following the effective date of the RPC Agreement. Under the terms of the RPC Agreement, the Buyer paid to the Company an aggregate cash amount of \$6,000,000 on October 5, 2022. In addition, the Buyer is obligated to pay up to \$4,500,000 to the Company based on mutually agreed upon revenue milestones during the calendar year 2023.

Melt Loan Amendments

In April and September 2022, we entered into a First Amendment and Second Amendment (collectively the “Amendments”) to our loan and security agreement previously entered into on September 1, 2021 with Melt. The Amendments provide for the following:

- Melt is required to maintain a minimum cash balance of \$7,000,000 for one year following the effective date of the Second Amendment; and a minimum cash balance of \$5,000,000 at all times after the one-year anniversary of the effective date of the Amendments.
- The maturity date by which all amounts owed under the loan agreement are payable was extended to June 1, 2023, which can be extended further to September 1, 2026 following a qualified financing of at least \$10,000,000, unless otherwise accelerated pursuant to the terms of the loan agreement.
- The definition of “material adverse effect” was amended so that such an effect will be deemed to have occurred if the data from the Phase 2 study of MELT-300 fails to demonstrate the benefit of the combination MELT-300 study drug versus the individual components of the same MELT-300 study drug, as reasonably determined by us.

Results of Operations

The following period-to-period comparisons of our financial results for the three and nine months ended September 30, 2022 and 2021 are not necessarily indicative of results for any future period.

Revenues

Our revenues include amounts recorded from sales of proprietary compounded formulations, sales of branded products to wholesalers through a third-party logistics facility, 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, 2022 and 2021:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2022	2021	Variance	2022	2021	Variance
Product sales, net	\$ 21,575,000	\$ 17,811,000	\$ 3,764,000	\$ 63,433,000	\$ 50,056,000	\$ 13,377,000
Commission revenues	1,044,000	900,000	144,000	3,576,000	2,212,000	1,364,000
Transfer of profits	204,000	-	204,000	1,257,000	-	1,257,000
License revenues	-	-	-	-	20,000	(20,000)
Total revenues	<u>\$ 22,823,000</u>	<u>\$ 18,711,000</u>	<u>\$ 4,112,000</u>	<u>\$ 68,266,000</u>	<u>\$ 52,288,000</u>	<u>\$ 15,978,000</u>

The increase in revenues between periods was related to an increase in sales volumes of our ophthalmology products, an increase in commissions attributable to sales of Dexycu® and transfer of profits from recently acquired products. In June of 2022, the Company completed the transfer from the seller to Harrow of Iopidine and Maxitrol NDAs and relaunched those products, as a result, we will not record revenues associated with the transfer of profits associated with those products in future periods.

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, 2022 and 2021:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2022	2021	Variance	2022	2021	Variance
Cost of sales	<u>\$ 6,721,000</u>	<u>\$ 4,947,000</u>	<u>\$ 1,774,000</u>	<u>\$ 19,218,000</u>	<u>\$ 13,134,000</u>	<u>\$ 6,084,000</u>

The increase in our cost of sales between periods was largely attributable to an increase in unit volumes sold and increased direct and indirect costs associated with production of our products.

Gross Profit and Margin

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2022	2021	Variance	2022	2021	Variance
Gross profit	<u>\$ 16,102,000</u>	<u>\$ 13,764,000</u>	<u>\$ 2,338,000</u>	<u>\$ 49,048,000</u>	<u>\$ 39,154,000</u>	<u>\$ 9,894,000</u>
Gross margin	<u>70.6%</u>	<u>73.6%</u>	<u>-3.0%</u>	<u>71.8%</u>	<u>74.9%</u>	<u>-3.1%</u>

The decrease in gross margin between the three and nine months ended September 30, 2022 and 2021 is primarily attributable to amortization of acquired NDAs beginning in January 2022, along with a one-time adverse production related event in April 2022, increased discounts provided during 2022 associated with volume-based purchases and increased (direct and indirect) production costs incurred during 2022.

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, 2022 and 2021:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2022	2021	Variance	2022	2021	Variance
Selling, general and administrative	<u>\$ 15,421,000</u>	<u>\$ 11,356,000</u>	<u>\$ 4,065,000</u>	<u>\$ 43,004,000</u>	<u>\$ 28,643,000</u>	<u>\$ 14,361,000</u>

The increase in selling, general and administrative expenses between periods was primarily attributable to an increase in consulting expenses associated with regulatory improvements, to support the transition of recent product acquisitions, and an increase in expenses related to the addition of new employees in sales, marketing and other departments to support current and expected growth, including the anticipated commercial launch of IHEEZO in 2023.

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, 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, 2022 and 2021:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2022	2021	Variance	2022	2021	Variance
Research and development	<u>\$ 775,000</u>	<u>\$ 6,125,000</u>	<u>\$ (5,350,000)</u>	<u>\$ 2,347,000</u>	<u>\$ 7,142,000</u>	<u>\$ (4,795,000)</u>

During the three and nine months ended September 30, 2022, research and development expenses decreased from the same periods in 2021 primarily as a result of a one-time payment for acquired research and development incurred in 2021 related to the acquisition of IHEEZO.

Interest Expense, Net

Interest expense, net was \$1,800,000 and \$5,386,000 for the three and nine months ended September 30, 2022, respectively, compared to \$1,685,000 and \$3,512,000 for the same periods in 2021, respectively. The increase during the period ended September 30, 2022 compared to the same periods in 2021 was primarily the result of an increase in the outstanding principal amount of our debt obligations.

Equity in Losses of Unconsolidated Entities

During the three and nine months ended September 30, 2022, we recorded a loss of \$3,504,000 and \$9,036,000, respectively, related to our share of losses in Melt, compared to \$706,000 and \$2,967,000 for the same periods last year, respectively.

Investment Loss from Eton

During the three and nine months ended September 30, 2022, we recorded a loss of \$1,031,000 and \$4,341,000, respectively, related to the change in fair market value of Eton’s common stock compared to losses of \$2,220,000 and \$8,639,000 for the same periods last year, respectively.

Gain on Forgiveness of PPP Loan

During the nine months ended September 30, 2021, we recorded a gain \$1,967,000 related to the forgiveness of our \$1,967,000 loan received pursuant to the Paycheck Protection Program under the Federal Coronavirus Aid, Relief, and Economic Security Act.

Net Loss

The following table presents our net loss and per share net loss for the three and nine months ended September 30, 2022 and 2021:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator – net loss attributable to Harrow Health, Inc. common stockholders	\$ (6,464,000)	\$ (8,328,000)	\$ (15,141,000)	\$ (10,589,000)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.31)	\$ (0.55)	\$ (0.42)

Liquidity and Capital Resources

Liquidity

Our cash on hand at September 30, 2022 was \$44,959,000, compared to \$42,167,000 at December 31, 2021.

As of the date of this Quarterly Report, we believe that cash and cash equivalents of \$44,959,000 at September 30, 2022 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 investments in Eton, Surface, Melt, and/or any of our consolidated subsidiaries. However, we may pursue acquisitions of 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,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ 5,417,000	\$ 6,572,000
Investing activities	(1,738,000)	(4,489,000)
Financing activities	(887,000)	51,472,000
Net change in cash and cash equivalents	2,792,000	53,555,000
Cash and cash equivalents at beginning of the period	42,167,000	4,301,000
Cash and cash equivalents at end of the period	\$ 44,959,000	\$ 57,856,000

Operating Activities

Net cash provided by operating activities during the nine months ended September 30, 2022 was \$5,417,000 compared to \$6,572,000 during the same period in the prior year. The decrease in net cash provided by operating activities between the periods was mainly attributed to increased operating expenses associated with planned 2023 commercial launch of IHEEZO and increased costs of goods sold.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2022 was \$(1,738,000) compared to \$(4,489,000) during the same period in the prior year. Cash used in investing activities in 2022 was primarily associated with equipment and software purchases. Cash used in investing activities in 2021 was primarily associated with the issuance of a note receivable to Melt and partially offset by cash provided by the sale of a portion of our investment in Eton.

Financing Activities

Net cash (used in) provided by financing activities during the nine months ended September 30, 2022 and 2021 was \$(887,000) and \$51,472,000, respectively. Cash used in financing activities during the nine months ended September 30, 2022 was primarily related to payment of payroll taxes upon vesting of RSUs in exchange for shares withheld from the employees. 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 and branded pharmaceutical business, and in 2021, proceeds from the sale of senior notes and a portion of our 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 the COVID-19 pandemic worsens 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, 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, 2022. 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, 2022, the end of the period covered by this Quarterly 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, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings

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

In addition to the other information contained in this Quarterly Report you should consider the risk factors and the other information in our Annual Report on Form 10-K for the year ended December 31, 2021, including our audited financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” If any such risks actually occur, 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.

There are many competitive risks related to marketing and selling our proprietary formulations and operating our compounding pharmacy business.

The pharmaceutical and pharmacy industries are highly competitive. We compete against branded drug companies, generic drug companies, outsourcing facilities and other compounding pharmacies. We are significantly smaller than some of our competitors. Currently we lack some of the financial and other resources needed to develop, produce, distribute and market our proprietary formulations at a level to capture a significant market share in these sectors. The drug products available through branded and generic drug companies with which our formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. Although we prepare our compounded formulations in accordance with the standards provided by the United States Pharmacopeia (“USP”) chapters <795> and <797> and applicable state and federal law, our proprietary compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, our formulations. Additionally, under federal and state laws applicable to our current compounding pharmacy operations, we are not permitted to prepare significant amounts of a specific formulation in advance of a prescription, compound quantities for office use or utilize a wholesaler for distribution of our formulations; instead, our compounded formulations must be prepared and dispensed in connection with a physician prescription for an individually identified patient. Pharmaceutical companies, on the other hand, are able to sell their FDA-approved products to large pharmaceutical wholesalers, which can in turn sell to and supply hospitals and retail pharmacies. Even if we are successful in registering certain of our facilities as outsourcing facilities, our business may not be scalable on the scope available to our competitors that produce FDA-approved drugs, which may limit our potential for profitable operations. These facets of our operations may subject our business to limitations our competitors with FDA-approved drugs may not face.

In November 2022, USP published finalized revisions to USP chapters <795> and <797>, which had been previously proposed for public comment in September 2021. The revisions include limitations on beyond use dating of sterile and preservative-free products and batch sizes, among other changes. USP expects the published revisions to become effective November 1, 2023, however, regulatory bodies such as state boards of pharmacy may adopt these changes at that time, or on different dates, on a case-by-case basis. While USP has no role in enforcement, we believe the revisions to USP chapter <797> in particular will likely cause two changes to our business, which in the aggregate should have a neutral to positive revenue impact on Harrow: (i) we expect a reduction in revenues generated from sales of formulations compounded by our 503A pharmacy, and (ii) we expect an increase in revenues from sales of formulations compounded in our 503B facility. Further, we believe the changes to USP chapter <797> will likely cause a reduction in the ability of local 503A pharmacies to produce compounded formulations to serve local markets, and that these changes in policy affecting sterile compounded formulations, if adopted by the various states, may increase demand for compounded formulations from larger vendors such as Harrow and cause further consolidation in the market for compounded formulations as smaller 503A pharmacies see a reduction in revenues from certain segments of their formularies affected by these changes.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
10.1*	First Amendment to Loan and Security Agreement, dated as of April 8, 2022, between the Company and Melt Pharmaceuticals, Inc.
10.2*	Second Amendment to Loan and Security Agreement, dated as of September 21, 2022, between the Company and Melt Pharmaceuticals, Inc.
10.3*	Mutual Termination Agreement, dated October 7, 2022 between ImprimisRx and EyePoint Pharmaceuticals, Inc.
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, 2022, has been formatted in Inline XBRL.

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

Harrow Health, Inc.

Dated: November 14, 2022

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)

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT (this “**Amendment**”) dated as of April 8, 2022 (the “**Amendment Effective Date**”), is made among HARROW HEALTH, INC., a Delaware corporation (“**Lender**”), MELT PHARMACEUTICALS, INC., a Delaware corporation (“**Borrower**”), and certain subsidiaries of the Borrower from time to time party to the Loan and Security Agreement as guarantors (defined below) (each a “**Guarantor**” and collectively, jointly and severally, “**Guarantors**” and collectively with the Borrower, each a “**Loan Party**” and collectively, the “**Loan Parties**”).

RECITALS

A. Loan Parties and Lender are parties to a Loan and Security Agreement, dated as of September 1, 2021 (as may be amended, restated, supplemented or otherwise modified from time to time, the “**Loan and Security Agreement**”).

B. Borrower has requested that Lender agree to certain amendments to the Loan and Security Agreement. Lender has agreed to such request, subject to the terms and conditions hereof.

AGREEMENTS

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Amendment, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

SECTION 1. Defined Terms; Interpretation.

(a) **Terms Defined in Loan and Security Agreement.** All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation.** The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2. Amendments to the Loan and Security Agreement.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(i) **New Definitions.** The following definitions are hereby added to Exhibit A in their proper alphabetical order:

“**Cash Equivalents**” shall mean (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having a rating of at least A-1 from Standard & Poor’s Ratings Group or at least a P-1 from Moody’s Investors Service, Inc.; (c) certificates of deposit, time deposits, overnight bank deposits or bankers’ acceptances maturing within one (1) year from the date of acquisition thereof issued by any bank organized under the laws of the United States or any state thereof or the District of Columbia or any United States branch of a foreign bank having at the date of acquisition thereof combined capital and surplus of not less than \$500,000,000; and (d) other short term liquid investments reasonably acceptable to Lender.”

“First Amendment” shall mean that certain First Amendment to Loan and Security Agreement, dated as of April 8, 2022, by and among the Lender and the Loan Parties.”

“Liquidity” shall mean the aggregate amount of unrestricted cash on hand and Cash Equivalents of a Person.”

(ii) Amended and Restated Definitions. The definitions of “Material Adverse Effect” and “Maturity Date” in Exhibit A are hereby amended and restated in their entirety as follows:

“Material Adverse Effect” shall mean a material adverse effect on (i) the business operations, properties, assets or condition (financial or otherwise) of the Loan Parties taken as a whole; (ii) the ability of any Loan Party to fully and timely perform its Obligations; (iii) the legality, validity, binding effect, or enforceability against a Loan Party of a Loan Document to which it is a party; or (iv) the rights and remedies available to, or conferred upon, Lender. Further, a Material Adverse Effect shall be deemed to have occurred in the event that data from the phase 2 study of MELT-300 failed to demonstrate the benefit of the combination MELT-300 study drug versus the individual components of the same MELT-300 study drug, as reasonably determined by Lender.”

“Maturity Date” means, the earlier of (a) September 1, 2026 (or if such date is not a Business Day, on the next Business Day after such date), and (b) the date on which the maturity date of the Loan accelerates after or upon an Event of Default.”

(iii) Access to Bank Accounts. The following language is hereby added as a new Section 5.15 (Access to Bank Accounts):

“5.15 Access to Bank Accounts. Each Loan Party will provide Lender with monthly bank statements, view access to such accounts, and any information or documentation reasonably required or requested by Lender to evidence any amounts held in such accounts.”

(iv) Financial Covenants. The following language is hereby added as a new Section 6.15 (Financial Covenants):

“6.15 Financial Covenants.

(a) Minimum Liquidity. Borrower shall not permit Liquidity to be less than (a) \$7,000,000 at all times during the period beginning on the date Borrower has consummated a Qualifying Financing (as defined in the First Amendment) and ending on the date that is one (1) year thereafter (the “Liquidity Adjustment Date”) and (b) \$5,000,000 at all times after the Liquidity Adjustment Date and continuing until the Maturity Date.”

(b) References Within Loan and Security Agreement. Each reference in the Loan and Security Agreement to “this Agreement” and the words “hereof,” “herein,” “hereunder,” or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3. Conditions of Effectiveness. Except as set forth in this Section 3, this Amendment shall become effective as of the date on which Borrower shall have delivered to Lender this Amendment duly executed by an authorized officer of Borrower, and Lender shall have executed and delivered this Amendment. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent; *provided*, that the requirements of Section 3(c) below are satisfied no later than August 31, 2022 (or such later date as Lender may agree in its sole discretion):

(a) **Fees and Expenses.** Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 5(c), and (ii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **Representations and Warranties; No Default.** On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 herein shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There shall exist no Events of Default or events that with the passage of time would result in an Event of Default.

(c) **Consummation of Qualifying Financing.** Lender shall have received evidence in form and substance acceptable to Lender in its reasonable discretion that Borrower has consummated a Qualifying Financing. For purposes of this Section 3(c), “**Qualifying Financing**” means (i) the issuance by Borrower of its common Equity Interests in an underwritten primary public offering (other than a public offering pursuant to a registration statement on Form S-8) that results in such common Equity Interests being publicly traded on any United States national securities exchange or over the counter market resulting in cash gross proceeds to Borrower of at least \$15,000,000; or (ii) the closing of any bona-fide equity financing with third party investors resulting in cash gross proceeds to Borrower of at least \$15,000,000.

(d) **Officer’s Certificate.** Lender shall have received a certificate from an officer of the Borrower, in form and substance satisfactory to the Lender in its reasonable discretion, certifying that the conditions set forth in this Section 3 have been satisfied.

SECTION 4. Representations and Warranties. To induce Lender to enter into this Amendment, each Loan Party hereby confirms, as of the date hereof, that:

(a) the representations and warranties made by it in Section 4 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided, however*, that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct in all material respects as of such prior date, *provided, further*, that in each case such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof;

(b) there has not been and there does not exist a Material Adverse Effect;

(c) Lender has and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted to Lender pursuant to the Loan Documents;

(d) the agreements and obligations of each Loan Party contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of such Loan Party, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors’ rights or by the application of general principles of equity; and

(e) the execution, delivery and performance of this Amendment by the Loan Parties will not violate any law, rule, regulation, order, material contractual obligation or organizational document of any Loan Party and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues (other than any liens, claims or encumbrances created or permitted under any of the Loan Documents); and

(f) except as disclosed to Lender, no Loan Party has amended its organizational documents since the date of the Loan Documents.

For the purposes of this Section 4, each reference in Section 5 of the Loan and Security Agreement to “this Agreement,” and the words “hereof,” “herein,” “hereunder,” or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 5. Miscellaneous.

(a) Loan Documents Otherwise Not Affected; Reaffirmation; No Novation.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lender’s execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Each Loan Party hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan and Security Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3.1 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, as of the date hereof, and with effect from (and including) the Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a “Loan Document” under the Loan and Security Agreement and (5) agrees that the Loan and Security Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of any Loan Party’s Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Lender’s security interest in, security titles to or other liens on any Collateral for the Obligations.

(b) **No Reliance.** Each Loan Party hereby acknowledges and confirms to Lender that such Loan Party is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(c) **Costs and Expenses.** Borrower agrees to pay to Lender within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the reasonable and out-of-pocket costs and expenses of Lender, and the reasonable and out-of-pocket fees and disbursements of counsel to Lender, in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(d) **Binding Effect.** This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(e) **Governing Law.** THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF DELAWARE (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF DELAWARE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.

(f) **Complete Agreement; Amendments.** This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(g) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(h) **Counterparts.** This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission, including by electronic signature, will be as effective as delivery of a manually executed counterpart hereof.

(i) **Loan Documents.** This Amendment and the documents related thereto shall constitute Loan Documents.

(j) **Release.** For and in consideration of Lender's agreements contained in this Amendment and as a material inducement to Lender to enter into this Amendment on which Lender is relying, each Loan Party, for and on behalf of itself and all of its respective direct or indirect parents, divisions, subsidiaries, affiliates, members, managers, participants, predecessors, successors, and assigns, and each of their respective current and former directors, officers, shareholders, members, managers, partners, agents, and employees, and each of their respective predecessors, successors, heirs, and assigns (collectively, "**Releasors**"), each intending to be legally bound, hereby voluntarily, intentionally and knowingly releases and forever waives and discharges the Released Parties of and from any and all claims existing on or before the Amendment Effective Date and which relate to or arise out of (i) any or all of the Loan Documents or transactions contemplated thereby or any actions or omissions in connection therewith, (ii) any aspect of the dealings or relationships between or among any or all of the Loan Parties, on the one hand, and any or all of the Released Parties, on the other hand, relating to any or all of the documents, transactions, actions or omissions referenced in clause (i) hereof, or (iii) the negotiation for and execution of this Amendment (including, without limitation, any contracting for, charging, taking, reserving, collecting or receiving interest in excess of the highest lawful rate applicable), irrespective of whether any such claims arise out of contract, tort, violation of law or regulations, or otherwise, and the Loan Parties, for themselves and the other Releasors, waive all defenses with respect to the enforcement by any Released Party of the provisions of the release set forth herein.

[Signatures Appear on the Following Page]

LENDER:

HARROW HEALTH, INC.

By: /s/ Andrew Boll

Title: Chief Financial Officer

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed as of the date first written above.

LOAN PARTIES:

MELT PHARMACEUTICALS, INC.

By: /s/ Larry Dillaha

Name: Larry Dillaha

Title: Chief Executive Officer

Signature Page to First Amendment to Loan & Security Agreement

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT (this “**Amendment**”) dated as of September 21, 2022 (the “**Amendment Effective Date**”), is made among HARROW HEALTH, INC., a Delaware corporation (“**Lender**”), MELT PHARMACEUTICALS, INC., a Delaware corporation (“**Borrower**”), and certain subsidiaries of the Borrower from time to time party to the Loan and Security Agreement as guarantors (defined below) (each a “**Guarantor**” and collectively, jointly and severally, “**Guarantors**” and collectively with the Borrower, each a “**Loan Party**” and collectively, the “**Loan Parties**”).

RECITALS

A. The Loan Parties and Lender are parties to a Loan and Security Agreement, dated as of September 1, 2021 (as amended by the First Amendment (defined below) and as further amended, restated, supplemented or otherwise modified from time to time, the “**Loan and Security Agreement**”).

B. The Loan Parties and Lender entered into a First Amendment to Loan and Security Agreement, dated as of April 8, 2022 (the “**First Amendment**”).

C. Borrower failed to pay the entire outstanding principal amount of the Loan and all accrued and unpaid Obligations pertaining thereto on or before the Maturity Date in violation of Section 1.7 of the Loan and Security Agreement and failed to provide notice thereof in violation of Section 5.8 of the Loan and Security Agreement, and such violations resulted in an Event of Default under Sections 8.1(a) and 8.1(d)(i) of the Loan and Security Agreement (collectively, the “**Specified Event of Default**”).

D. Borrower has requested that Lender agree to (i) waive the Specified Event of Default, and (ii) amend the Loan and Security Agreement to, among other things, extend the Maturity Date. Lender has agreed to such requests, subject to the terms and conditions hereof.

AGREEMENTS

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Amendment, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

SECTION 1. Defined Terms; Interpretation.

(a) **Terms Defined in Loan and Security Agreement.** All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation.** The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2. Amendments to the Loan and Security Agreement.**(a) Effective Date Amendments.**

(i) **Amended and Restated Definition.** The definition of “Maturity Date” in Exhibit A to the Loan and Security Agreement is hereby amended and restated in its entirety as follows: “Maturity Date” means, the earlier of (a) June 1, 2023 (or if such date is not a Business Day, on the next Business Day after such date), and (b) the date on which the maturity date of the Loan accelerates after or upon an Event of Default.

(ii) New Definition. The following definition is hereby added to Exhibit A in its proper alphabetical order:

“Qualifying Financing” means (a) the issuance by Borrower of its common equity interests in an underwritten primary public offering (other than a public offering pursuant to a registration statement on Form S-8) that results in such common equity interests being publicly traded on any United States national securities exchange or over the counter market resulting in cash gross proceeds to Borrower of at least \$10,000,000; or (b) the closing of any bona-fide equity financing with third party investors resulting in cash gross proceeds to Borrower of at least \$10,000,000.

(b) **Post-QF Amendments**. The Loan and Security Agreement shall be amended as follows effective as of the Post-QF Amendment Effective Date (defined below):

(i) New Definitions. The following definitions are hereby added to Exhibit A in their proper alphabetical order:

“Cash Equivalents” shall mean (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having a rating of at least A-1 from Standard & Poor’s Ratings Group or at least a P-1 from Moody’s Investors Service, Inc.; (c) certificates of deposit, time deposits, overnight bank deposits or bankers’ acceptances maturing within one (1) year from the date of acquisition thereof issued by any bank organized under the laws of the United States or any state thereof or the District of Columbia or any United States branch of a foreign bank having at the date of acquisition thereof combined capital and surplus of not less than \$500,000,000; and (d) other short term liquid investments reasonably acceptable to Lender.

“Liquidity” shall mean the aggregate amount of unrestricted cash on hand and Cash Equivalents of a Person.

(ii) Amended and Restated Definitions. The definitions of “Material Adverse Effect” and “Maturity Date” in Exhibit A are hereby amended and restated in their entirety as follows:

“Material Adverse Effect” shall mean a material adverse effect on (a) the business operations, properties, assets or condition (financial or otherwise) of the Loan Parties taken as a whole; (b) the ability of any Loan Party to fully and timely perform its Obligations; (c) the legality, validity, binding effect, or enforceability against a Loan Party of a Loan Document to which it is a party; or (d) the rights and remedies available to, or conferred upon, Lender. Further, a Material Adverse Effect shall be deemed to have occurred in the event that data from the phase 2 study of MELT-300 failed to demonstrate the benefit of the combination MELT-300 study drug versus the individual components of the same MELT-300 study drug, as reasonably determined by Lender.

“Maturity Date” means, the earlier of (a) September 1, 2026 (or if such date is not a Business Day, on the next Business Day after such date), and (b) the date on which the maturity date of the Loan accelerates after or upon an Event of Default.

(iii) Access to Bank Accounts. The following language is hereby added as a new Section 5.15 (Access to Bank Accounts):

5.15 Access to Bank Accounts. Each Loan Party will provide Lender with monthly bank statements, view access to such accounts, and any information or documentation reasonably required or requested by Lender to evidence any amounts held in such accounts.

(iv) Financial Covenants. The following language is hereby added as a new Section 6.15 (Financial Covenants):

6.15 Financial Covenants.

(a) Minimum Liquidity. Borrower shall not permit Liquidity to be less than (a) \$7,000,000 at all times during the period beginning on the date Borrower has consummated a Qualifying Financing and ending on the date that is one (1) year thereafter (the “Liquidity Adjustment Date”) and (b) \$5,000,000 at all times after the Liquidity Adjustment Date and continuing until the Maturity Date.

(c) **References Within Loan and Security Agreement.** Each reference in the Loan and Security Agreement to “this Agreement” and the words “hereof,” “herein,” “hereunder,” or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3. Limited Waiver.

(a) Borrower hereby agrees and acknowledges, and represents and warrants to Lender, that the Specified Event of Default has occurred, is continuing and is not subject to cure or has not been cured within the applicable cure period.

(b) At the request of and as an accommodation to Borrower and subject to the terms and conditions set forth herein, Lender hereby waives the Specified Event of Default. The limited waiver set forth in this Section 3 is effective solely for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to, except as expressly provided herein with respect to the Specified Event of Default, (i) be a consent to any amendment, waiver or modification of any term or condition of the Loan and Security Agreement or of any other Loan Document; (ii) prejudice any right that Lender has or may have in the future under or in connection with the Loan and Security Agreement or of any other Loan Document; (iii) waive any Event of Default that may exist as of the date hereof; or (iv) waive compliance with the Loan and Security Agreement with respect to any Loan Party or transaction. The limited waiver set forth in this Section 3 shall not be deemed to establish a custom or course of dealing among any of the Loan Parties, on the one hand, or Agent or any Lender, on the other hand.

SECTION 4. Conditions of Effectiveness. Except as set forth in this Section 4 and Section 5, this Amendment shall become effective as of the date on which Borrower shall have delivered to Lender this Amendment duly executed by an authorized officer of Borrower, and Lender shall have executed and delivered this Amendment. The effectiveness of Sections 2(a) and 3 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses.** Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 7(c), and (ii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **Representations and Warranties; No Default.** On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement and the limited waiver contemplated hereby:

(i) The representations and warranties contained in Section 6 herein shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There shall exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 5. Conditions of Effectiveness. Section 2(b) of this Amendment shall be effective on the date on which each of the following conditions precedent is satisfied (the “**Post-QF Amendment Effective Date**”); *provided*, that such date occurs no later than May 31, 2023 (or such later date as Lender may agree in its sole discretion):

(a) **Fees and Expenses.** Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 7(c), and (ii) all other fees, costs and expenses, if any, due and payable as of the Post-QF Amendment Effective Date under the Loan and Security Agreement.

(b) **Representations and Warranties; No Default.** On the Post-QF Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 6 herein shall be true and correct on and as of the Post-QF Amendment Effective Date as though made on and as of such date; and

(ii) There shall exist no Events of Default or events that with the passage of time would result in an Event of Default.

(c) **Consummation of Qualifying Financing.** Lender shall have received evidence in form and substance acceptable to Lender in its reasonable discretion that Borrower has consummated a Qualifying Financing.

(d) **Officer’s Certificate.** Lender shall have received a certificate from an officer of the Borrower, in form and substance satisfactory to the Lender in its reasonable discretion, certifying that the conditions set forth in this Section 5 have been satisfied.

SECTION 6. Representations and Warranties. To induce Lender to enter into this Amendment, each Loan Party hereby confirms, as of the date hereof, that:

(a) giving effect to this Amendment, the representations and warranties made by it in Section 4 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided, however*, that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct in all material respects as of such prior date, *provided, further*, that in each case such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof;

(b) giving effect to this Amendment, there has not been and there does not exist a Material Adverse Effect;

(c) Lender has and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted to Lender pursuant to the Loan Documents;

(d) the agreements and obligations of each Loan Party contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of such Loan Party, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and

(e) the execution, delivery and performance of this Amendment by the Loan Parties will not violate any law, rule, regulation, order, material contractual obligation or organizational document of any Loan Party and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues (other than any liens, claims or encumbrances created or permitted under any of the Loan Documents); and

(f) except as disclosed to Lender, no Loan Party has amended its organizational documents since the date of the Loan Documents.

For the purposes of this Section 6, each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 7. Miscellaneous.

(a) Loan Documents Otherwise Not Affected; Reaffirmation; No Novation.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lender's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Each Loan Party hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan and Security Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3.1 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, as of the date hereof, and with effect from (and including) each of the Amendment Effective Date and the Post-QF Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan and Security Agreement and (5) agrees that the Loan and Security Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of any Loan Party's Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Lender's security interest in, security titles to or other liens on any Collateral for the Obligations.

(b) **No Reliance.** Each Loan Party hereby acknowledges and confirms to Lender that such Loan Party is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(c) **Costs and Expenses.** Borrower agrees to pay to Lender within ten (10) days of its receipt of an invoice (or on the Post-QF Amendment Effective Date to the extent invoiced on or prior to the Post-QF Amendment Effective Date), the reasonable and out-of-pocket costs and expenses of Lender, and the reasonable and out-of-pocket fees and disbursements of counsel to Lender, in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Post-QF Amendment Effective Date or after such date.

(d) **Binding Effect.** This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(e) **Governing Law.** **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF DELAWARE (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF DELAWARE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(f) **Complete Agreement; Amendments.** This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(g) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(h) **Counterparts.** This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission, including by electronic signature, will be as effective as delivery of a manually executed counterpart hereof.

(i) **Loan Documents.** This Amendment and the documents related thereto shall constitute Loan Documents.

(j) **Release.** For and in consideration of Lender's agreements contained in this Amendment and as a material inducement to Lender to enter into this Amendment on which Lender is relying, each Loan Party, for and on behalf of itself and all of its respective direct or indirect parents, divisions, subsidiaries, affiliates, members, managers, participants, predecessors, successors, and assigns, and each of their respective current and former directors, officers, shareholders, members, managers, partners, agents, and employees, and each of their respective predecessors, successors, heirs, and assigns (collectively, "**Releasors**"), each intending to be legally bound, hereby voluntarily, intentionally and knowingly releases and forever waives and discharges the Released Parties of and from any and all claims existing on or before the Amendment Effective Date and which relate to or arise out of (i) any or all of the Loan Documents or transactions contemplated thereby or any actions or omissions in connection therewith, (ii) any aspect of the dealings or relationships between or among any or all of the Loan Parties, on the one hand, and any or all of the Released Parties, on the other hand, relating to any or all of the documents, transactions, actions or omissions referenced in clause (i) hereof, or (iii) the negotiation for and execution of this Amendment (including, without limitation, any contracting for, charging, taking, reserving, collecting or receiving interest in excess of the highest lawful rate applicable), irrespective of whether any such claims arise out of contract, tort, violation of law or regulations, or otherwise, and the Loan Parties, for themselves and the other Releasors, waive all defenses with respect to the enforcement by any Released Party of the provisions of the release set forth herein.

[Signatures Appear on the Following Page]

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed as of the date first written above.

LOAN PARTIES:

MELT PHARMACEUTICALS, INC.

By: /s/ Larry Dillaha

Name: Larry Dillaha

Title: Chief Executive Officer

Signature Page to Second Amendment to Loan & Security Agreement

LENDER:

HARROW HEALTH, INC.

By: /s/ Andrew Boll

Name: Andrew R. Boll

Title: Chief Financial Officer

Signature Page to Second Amendment to Loan & Security Agreement

October 7, 2022

VIA EMAIL

Imprimis Rx, LLC
12264 El Camino Real
Suite 350
San Diego, California 92130
Attn: John Saharek
Email: jsaharek@imprimisrx.com

Re: Commercial Alliance Agreement: Mutual Termination

Dear John:

EyePoint Pharmaceuticals, Inc. (“**EyePoint**”) and ImprimisRx, LLC (“**Imprimis**”) entered into a Commercial Alliance Agreement effective as of August 1, 2020, as modified by the Letter Agreement dated November 12, 2020, and by the further Letter Agreement dated December 6, 2021 (collectively, the “**Agreement**”). Capitalized terms used but not defined in this letter have their respective meanings set forth in the Agreement. The change to the Agreement described below shall be effective October 1, 2022 (the “**Change Effective Date**”), and the mutual termination of the Agreement described below shall be effective as of January 1, 2023 (the “**Mutual Termination Effective Date**”). For good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

Consistent Efforts; Change to the Agreement:

Notwithstanding anything to the contrary in the Agreement, the Parties mutually agree that until the Mutual Termination Effective Date, the Parties shall provide a level of time, staffing, effort and support of the Product and of the other obligations under the Agreement that is consistent with each Party’s level of engagement during January-June 2022.

Further, and subject to the Consistent Efforts language above, the Parties mutually agree that effective from the Change Effective Date through the Mutual Termination Effective Date (i.e., Q4 2022), the following change shall apply:

- Imprimis shall achieve quarterly Customer demand milestones for the Product of at least 3,500 Dexycu units (“Minimum Quarterly Units” or “MQUs”).

Mutual Termination of the Agreement:

The Parties agree that, effective on the Mutual Termination Effective Date, the Agreement shall be deemed terminated by the mutual agreement of the Parties. The Parties further agree as follows:

- On or promptly following the Mutual Termination Effective Date, Imprimis will, at EyePoint's discretion, either promptly return to EyePoint or destroy any units of Product or other promotional materials related to the Agreement, in Imprimis' possession.
- As of the Mutual Termination Effective Date, and except as is set forth in Section 13.6.1, all obligations of Imprimis to EyePoint, and all obligations of EyePoint to Imprimis, under the Agreement, shall cease, the Commercialization Committee and the Joint Steering Committee shall be dissolved. Except as required pursuant to Section 13.6.1, all activities regarding the Product occurring on or after the Mutual Termination Effective Date shall be EyePoint's sole responsibility.
- Each Party shall, in accordance with Article 12 of the Agreement, indemnify and hold harmless the other Party, its sub-agents, its and their respective Affiliates, and its and their respective directors, officers, employees and agents, against all Liabilities resulting from such Party's activities or omissions related to the Agreement that occur before, on or after the Mutual Termination Effective Date.
- On or promptly following the Mutual Termination Effective Date, Imprimis shall cease all promotion of the Product, and shall transfer to EyePoint any websites and remove online references to the Product on any of its web pages or other promotional materials.
- For purposes of interpretation of the Agreement, as the result of the Parties' mutual agreement to terminate the Agreement, with the exception of the survival of Agreement sections described in Section 13.6.1, any clauses of the Agreement referring to the consequences of termination by one Party or by the other Party, for any reason or for no reason, shall be null and void and of no further force or effect.
 - By way of example and not of limitation, the following sections of the Agreement are hereby null and void and of no further force or effect: 13.6.2, 13.6.3, 13.6.4, 13.6.5.
- Section 13.6.1 of the Agreement is hereby amended and restated in its entirety to read as follows:

"13.6.1 The mutual termination of this Agreement shall be without prejudice to any rights which shall have accrued to the benefit of a Party prior to such expiration or termination. In addition, and without limiting the foregoing, Sections 1.1, 2.4, 4.3, 4.4, 5.7, 5.8, 8.4 (with respect to activities occurring in 2022), Article 9, Article 10, Article 12, Sections 13.6.1, 13.6.6 and Article 14 will survive the mutual termination of this Agreement, and Sections 8.5 and 8.6 shall survive for a period of five (5) years after such mutual termination."
- For a period of twelve (12) months following the Mutual Termination Effective Date, the Parties agree to mutually reconcile, in good faith, and to pay promptly any outstanding amounts due under the Agreement.

Additional Terms:

This letter will be governed by and construed under and in accordance with the laws of the State of Delaware, without regard to the conflicts of laws principles thereof.

Unless expressly modified by this Letter, all terms and conditions set forth in the Agreement shall remain in full force and effect until the Mutual Termination Effective Date.

If the foregoing is acceptable to you, please sign and return one fully-executed copy of this letter to us at your earliest convenience, which shall evidence your acknowledgement and acceptance thereto. This letter may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same document.

[Signature Page Follows.]

Very truly yours,

EyePoint Pharmaceuticals, Inc.

By: /s/ Nancy Lurker

Name: Nancy Lurker

Title: President & CEO

Agreed to and accepted:

ImprimisRx, LLC

By: /s/ John Saharek

Name: John Saharek

Title: President

Date: October 7, 2022

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 14, 2022

/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 14, 2022

/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, 2022 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 14, 2022

/s/ Mark L. Baum

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

Date: November 14, 2022

/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.
