# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

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

For the quarterly period ended March 31, 2021

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-35814

# Harrow Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

102 Woodmont Blvd., Suite 610 Nashville, Tennessee

(Address of principal executive offices)

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

**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  $\boxtimes$  No  $\square$ 

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

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

Large accelerated filer		Accelerated filer	
Non-accelerated filer	X	Smaller reporting company	X
		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 May 10, 2021, there were 26,582,215 shares of the registrant's common stock, \$0.001 par value, outstanding.

# HARROW HEALTH, INC.

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# PART I FINANCIAL INFORMATION

# Item 1. Financial Statements

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

	March 31, 2021		December 31, 2020	
	(1	inaudited)		
ASSETS				
Current assets				
Cash and cash equivalents, including restricted cash of \$200	\$	6,504	\$	4,301
Investment in Eton Pharmaceuticals		25,620		28,455
Accounts receivable, net		3,253		2,662
Inventories		4,496		3,962
Prepaid expenses and other current assets		763		751
Total current assets		40,636		40,131
Property, plant and equipment, net		4,200		4,453
Operating lease right-of-use assets		6,651		6,799
Intangible assets, net		1,912		1,939
Investment in Surface Ophthalmics		465		1,314
Investment in Melt Pharmaceuticals		2,056		2,506
Goodwill		332		332
TOTAL ASSETS	\$	56,252	\$	57,474
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Accounts payable and accrued expenses	\$	5,176	\$	3,932
Accrued payroll and related liabilities		1,631		2,315
Deferred revenue and customer deposits		3		66
Current portion of paycheck protection program loan payable		-		1,259
Current portion of loan payable, net of unamortized debt discount		2,659		2,639
Current portion of operating lease liabilities		597		580
Current portion of finance lease obligations		8		8
Total current liabilities		10,074		10,799
Operating lease liabilities, net of current portion		6,496		6,652
Finance lease obligations		16		17
Accrued expenses, net of current portion		800		800
Paycheck protection program loan payable, net of current portion		-		708
Loan payable, net of current portion and unamortized debt discount		10,996		11,670
TOTAL LIABILITIES		28,382		30,646
COMMITMENTS AND CONTINGENCIES				
STOCKHOLDERS' EQUITY				
Common stock, \$0.001 par value, 50,000,000 shares authorized, 25,983,676 and				
25,749,875 shares issued and outstanding at March 31, 2021 and December 31, 2020,				
respectively		26		26
Additional paid-in capital		105,382		104,557
Accumulated deficit		(77,183)		(77,400)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY		28,225		27,183
Noncontrolling interests		(355)		(355)
TOTAL EQUITY		27,870		26,828
TOTAL LIABILITIES AND EQUITY	\$	56,252	\$	57,474

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

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

	For the Three Months Ended March 31, 2021			For the Three Months Ended March 31, 2020	
Revenues:					
Product sales, net	\$	14,948	\$	11,810	
Other revenues		495		7	
Total revenues		15,443		11,817	
Cost of sales		(3,770)		(3,626)	
Gross profit		11,673		8,191	
Operating expenses:					
Selling, general and administrative		8,164		8,416	
Research and development		592		403	
Total operating expenses		8,756		8,819	
Income (loss) from operations		2,917		(628)	
Other income (expense):					
Interest expense, net		(513)		(560)	
Investment loss from Melt Pharmaceuticals		(470)		(546)	
Investment loss from Surface Ophthalmics		(849)		(339)	
Investment loss from Eton Pharmaceuticals		(2,835)		(10,850)	
Gain on forgiveness of debt		1,967		-	
Total other (expense), net		(2,700)		(12,295)	
Income (loss) before income taxes		217		(12,923)	
Income taxes		-		-	
Total net income (loss) including noncontrolling interests		217		(12,923)	
Net loss attributable to noncontrolling interests		_		16	
Net income (loss) attributable to Harrow Health, Inc.	\$	217	\$	(12,907)	
Basic net income (loss) per share of common stock	\$	0.01	\$	(0.50)	
Diluted net income (loss) per share of common stock	\$	0.01	\$	(0.50)	
Weighted average number of shares of common stock outstanding, basic		26,019,255		25,867,568	
Weighted average number of shares of common stock outstanding, diluted		27,480,622		25,867,568	

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

# HARROW HEALTH, INC. CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY For the three months ended March 31, 2021 and 2020 (In thousands, except for share data)

								Total			
							Ha	arrow Health,		Total	
	Common	Stoc	k	Additional				Inc.	No	oncontrolling	
		F	Par	Paid-in	Ac	cumulated	S	tockholders'	Equity		Total
	Shares	Vä	alue	Capital		Deficit		Equity		Interest	Equity
Balance at December 31, 2019	25,526,931	\$	26	\$ 101,728	\$	(74,043)	\$	27,711	\$	(293)	\$ 27,418
Issuance of common stock in connection with:											
Issuance of common stock related to vesting											
of RSUs	91,987		-	-		-		-		-	-
Stock-based compensation expense	-		-	533		-		533		-	533
Net loss			-			(12,907)		(12,907)		(16)	(12,923)
Balance at March 31, 2020	25,618,918	\$	26	\$ 102,261	\$	(86,950)	\$	15,337	\$	(309)	\$ 15,028
Balance at December 31, 2020	25,749,875	\$	26	\$ 104,557	\$	(77,400)	\$	27,183	\$	(355)	\$ 26,828
Issuance of common stock in connection with:											
Exercise of employee options	11,301		-	27		-		27		-	27
Issuance of common stock related to vesting											
of RSUs	230,000		-	-		-		-		-	-
Shares withheld related to net share											
settlement of equity awards	(7,500)		-	(57)		-		(57)		-	(57)
Stock-based compensation expense	-		-	855		-		855		-	855
Net income	-		-	-		217		217		-	217
Balance at March 31, 2021	25,983,676	\$	26	\$ 105,382	\$	(77,183)	\$	28,225	\$	(355)	\$ 27,870

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

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

		For the hree Months Ended arch 31, 2021		For the Ihree Months Ended Iarch 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES				
Net income (loss) (including noncontrolling interests)	\$	217	\$	(12,923)
Adjustments to reconcile net income (loss) to net cash provided by (used in)			*	( ))
operating activities:				
Depreciation and amortization of property, plant and equipment		464		448
Amortization of intangible assets		40		45
Amortization of operating lease right-of-use assets		148		169
Provision for bad debt expense		19		-
Amortization of debt issuance costs and discount		96		160
Gain on forgiveness of debt		(1,967)		-
Investment loss from Eton Pharmaceuticals		2,835		10,850
Investment loss from Surface Ophthalmics		849		339
Investment loss from Melt Pharmaceuticals		470		546
Stock-based compensation		855		533
Changes in assets and liabilities:				
Accounts receivable		(610)		(20)
Inventories		(534)		(688)
Prepaid expenses and other assets		(32)		(8)
Accounts payable and accrued expenses		1,105		(337)
Accrued payroll and related liabilities		(684)		333
Deferred revenue and customer deposits		(63)		3
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES		3,208		(550)
CASH FLOWS FROM INVESTING ACTIVITIES				
Investment in patent and trademark assets		(13)		(53)
Purchases of property, plant and equipment		(211)		(220)
NET CASH USED IN INVESTING ACTIVITIES		(224)		(273)
CASH FLOWS FROM FINANCING ACTIVITIES				
Payments on finance lease obligations		(1)		(2)
Principal payments on SWK loan		(750)		-
Net proceeds from exercise of stock options, net of taxes remitted upon vesting of RSU's				
and options		(30)		-
NET CASH USED IN FINANCING ACTIVITIES		(781)		(2)
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	-	2,203		(825)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period		4,301		4,949
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	\$	6,504	\$	4,124
	Ψ	0,504	Ψ	7,127
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH	\$	6,304	\$	3,924
Cash and cash equivalents Restricted cash	Э	200	Э	
	<u>.</u>		-	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	\$	6,504	\$	4,124
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Cash paid for income taxes	\$	-	\$	-
Cash paid for interest	\$	415	\$	408
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:				
Right-of-use asset obtained in exchange for lease obligation	\$	-	\$	41
Changes in accrued property and equipment purchases	\$		\$	5
	Ψ	-	Ψ	

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

# HARROW HEALTH, INC. NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS For the Three Months Ended March 31, 2021 and 2020 (All dollar amounts are expressed in thousands, except share and per share data)

# NOTE 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

## **Company and Background**

Harrow Health, Inc. (together with its subsidiaries, partially owned companies and royalty arrangements unless the context indicates or otherwise requires, the "Company" or "Harrow") specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace through its subsidiaries and deconsolidated companies. The Company owns one of the nation's leading ophthalmology-focused pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, the Company also has equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Ophthalmics, Inc. ("Surface"), and Melt Pharmaceuticals, Inc. ("Melt"), all companies that began as subsidiaries of Harrow. In 2020, Harrow created Visionology, Inc. ("Visionology"), which will launch an online eye health platform business. Harrow also owns royalty rights in various drug candidates being developed by Surface and Melt.

## **Basis of Presentation**

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and in accordance with the rules and regulations of the U.S. Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by GAAP for audited financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 or for any other period. For further information, refer to the Company's audited consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

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

Harrow consolidates entities in which it has a controlling financial interest. The Company consolidates subsidiaries in which it holds and/or controls, directly or indirectly, more than 50% of the voting rights. All intercompany accounts and transactions have been eliminated in consolidation.

The condensed consolidated balance sheets at March 31, 2021 and December 31, 2020 and the condensed consolidated statements of operations, stockholders' equity and cash flows for the periods ended March 31, 2021 and 2020 include our accounts and those of our wholly owned subsidiaries, as well as our inactive majority owned subsidiaries Mayfield Pharmaceuticals, Inc. and Stowe Pharmaceuticals, Inc.

# NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

# **Risks, Uncertainties and Liquidity**

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

#### Segments

The Company's chief operating decision-maker is its Chief Executive Officer who makes resource allocation decisions and assesses performance based on financial information of our operating segments. The Company has identified two operating segments as reportable segments. See Note 16 for more information regarding the Company's reportable segments.

# **Noncontrolling Interests**

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

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

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

# Basic and Diluted Net Income (Loss) per Common Share

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

Basic and diluted net income (loss) per share is computed using the weighted average number of shares of common stock outstanding during the period. Common equivalent shares (using the treasury stock or "if converted" method) from stock options, RSUs and warrants were 5,486,678 and 5,253,638 at March 31, 2021 and 2020, respectively. For the three months ended March 31, 2020, the common equivalent shares are excluded in the calculation of diluted net loss per share because the effect is anti-dilutive. Included in the basic and diluted net income (loss) per share calculation were RSUs awarded to directors that had vested, but the issuance and delivery of the shares are deferred until the director resigns. The number of shares underlying vested RSUs at March 31, 2021 and 2020 was 223,219 and 244,460, respectively.

The following table shows the computation of basic net income (loss) per share of common stock for the three months ended March 31, 2021 and 2020:

	For the Thi Ended M	
	 2021	 2020
Numerator – net income (loss) attributable to Harrow Health, Inc.	\$ 217	\$ (12,907)
Denominator – weighted average number of shares outstanding, basic	26,019,255	25,867,568
Net income (loss) per share, basic	\$ 0.01	\$ (0.50)

For the three months ended March 31, 2021, the Company computed diluted net income per share using the weighted-average number of common shares and dilutive common equivalent shares outstanding during the period. Diluted common equivalent shares for the three months ended March 31, 2021, consisted of the following:

	<b>March 31,</b> 2021
Diluted shares related to:	
Warrants	576,275
Stock options	885,092
Dilutive common equivalent shares	1,461,367



The following table shows the computation of diluted net income (loss) per share using the weighted-average number of common shares and dilutive common equivalent shares outstanding for the three months ended March 31, 2021 and 2020:

	_	For the Th Ended M		
		2021		2020
Numerator – net income (loss)	\$	217	\$	(12,907)
Weighted average number of shares outstanding, basic		26,019,255		25,867,568
Dilutive common equivalent shares		1,461,367		-
Denominator – number of shares used for diluted earnings per share computation		27,480,622	_	25,867,568
Net income (loss) per share, diluted	\$	0.01	\$	(0.50)

# Investment in Eton Pharmaceuticals, Inc.

As of March 31, 2021, the Company owned 3,500,000 shares of Eton common stock, which represented approximately 14.3% of the equity interests of Eton. At March 31, 2021, the fair market value of Eton's common stock was \$7.32 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 \$2,835 and \$10,850 during the three months ended March 31, 2021 and 2020, respectively, related to the change in fair market value of its investment in Eton during the measurement period. As of March 31, 2021, the fair market value of the Company's investment in Eton was \$25,620.

During the three months ended March 31, 2021, Mark L. Baum, the Company's Chief Executive Officer, resigned as a member of the board of directors of Eton. In April 2021, the Company sold 1,518,000 shares of its Eton common stock (see Note 17 for more information related to this subsequent event). In light of these events, the Company has determined that Eton is no longer a related party.

# Investment in Melt Pharmaceuticals, Inc. - Related Party

The Company owns 3,500,000 common shares (which is approximately 44% of the equity interests as of March 31, 2021) of Melt and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Melt. Under this method, the Company recognizes earnings and losses in Melt in its condensed consolidated financial statements and adjusts the carrying amount of its investment in Melt accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Melt. Any intra-entity profits and losses are eliminated. During the three months ended March 31, 2021 and 2020, the Company recorded equity in the net losses of Melt of \$470 and \$546, respectively. As of March 31, 2021 and December 31, 2020, the Company's investment in Melt was \$2,056 and \$2,506, respectively, which includes \$881 and \$851, respectively, due from Melt for reimbursable expenses and amounts due under a Management Services Agreement between the Company and Melt (the "Melt MSA").

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

## Investment in Surface Ophthalmics, Inc. - Related Party

The Company owns 3,500,000 common shares (which is approximately 30% of the equity interests as of March 31, 2021) of Surface and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, the Company recognizes earnings and losses in Surface in its condensed consolidated financial statements and adjusts the carrying amount of its investment in Surface accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Surface. Any intra-entity profits and losses are eliminated. The Company recorded equity in the net losses of Surface of \$849 and \$339 during the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021 and December 31, 2020, the Company's investment in Surface was \$465 and \$1,314, respectively.

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



# **Recently Adopted Accounting Pronouncements**

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

# NOTE 3. REVENUES

The Company accounts for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers*. The Company has three primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services, (2) revenue recognized from a commission agreement with a third party and (3) revenue recognized from intellectual property license and asset purchase agreements.

# Product Revenues from Pharmacy Services

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

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

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

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

# **Commission Revenues**

During the year ended December 31, 2020, the Company entered into an agreement whereby it is paid a fee calculated based on sales it generates from a pharmaceutical product that is owned by a third party. The revenue earned from this arrangement is recognized at the time a customer has ordered the pharmaceutical product and it has shipped from the third party (or one of its distributors or affiliates), at which point there is no future performance obligation required by the Company and no consequential continuing involvement on the part of the Company to recognize the associated revenue.



# Intellectual Property License Revenues

As of March 31, 2021, we are party to four intellectual property licenses and asset purchase agreements in which we have agreed to grant a license and which provide a customer with the right to access the Company's intellectual property. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive license rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements can be multiple-element arrangements, the revenue of which is recognized at the point in time at which the performance obligation is met.

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

Revenue disaggregated by revenue source for the three months ended March 31, 2021 and 2020, consists of the following:

	For the Thi Ended M	
	2021	2020
Product sales, net	\$ 14,948	\$ 11,810
Commissions	485	-
Licenses	10	7
Total revenues	\$ 15,443	\$ 11,817

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

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

In December 2018, the Company entered into an asset purchase agreement with Melt (the "Melt Asset Purchase Agreement"). Pursuant to the terms of the Melt Asset Purchase Agreement, Melt was assigned certain intellectual property and related rights from the Company to develop, formulate, make, sell, and sub-license certain Company conscious sedation and analgesia related formulations (collectively, the "Melt Products"). Under the terms of the Melt Asset Purchase Agreement, Melt is required to make mid-single-digit royalty payments to the Company on net sales of the Melt Products while any patent rights remain outstanding, as well as other conditions. In January and March 2019, the Company entered into the Melt Series A Preferred Stock Agreement. See also Note 2, under the subheading *Investment in Melt Pharmaceuticals, Inc.* 

In February 2019, the Company and Melt entered into the Melt MSA, whereby the Company provides to Melt certain administrative services and support, including bookkeeping, web services and human resources related activities, and Melt is required to pay the Company a monthly amount of \$10.

As of March 31, 2021 and December 31, 2020, the Company was due \$881 and \$851, respectively, from Melt for reimbursable expenses and amounts due under the Melt MSA. Melt did not make any payments to the Company during the three months ended March 31, 2021.

The Company's Chief Executive Officer, Mark L. Baum, and Chief Medical Officer, Larry Dillaha, M.D. are members of the Melt board of directors, and several employees of the Company (including Mr. Baum, Dr. Dillaha and the Company's Chief Financial Officer, Andrew R. Boll) entered into consulting agreements and provide consulting services to Melt.



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

For the Three Months Ended			
March	31, 2021 Marc	ch 31, 2020	
\$	- \$	-	
	(1,099)	(1,235)	
\$	(1,099) \$	(1,235)	
		March 31, 2021 Marc \$ - \$ (1,099)	

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

	At March 31, 2021		cember 31, 2020
Current assets	\$ 2,267	\$	2,947
Non-current assets	 79		11
Total assets	 2,346		2,958
Total liabilities	2,133		1,778
Total stockholders equity	 213		1,180
Total liabilities and stockholders' equity	\$ 2,346	\$	2,958

# 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 March 31, 2021, the Company owned 3,500,000 shares of Surface common stock (approximately 30% of the issued and outstanding equity interests). A Company director, Richard L. Lindstrom, and the Company's Chief Executive Officer, Mark L. Baum, are directors of Surface. Surface is required to make royalty payments to Dr. Lindstrom of 3% of net sales of certain Surface products while certain patent rights remain outstanding. Dr. Lindstrom is also a minority owner of Flying L Partners, an affiliate of the funding investor who purchased the Surface Series A Preferred Stock. Several employees and a director of the Company (including Mr. Baum and Dr. Lindstrom) entered into consulting agreements and provide consulting services to Surface.

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

r	For the Three	Mon	ths Ended
	March 31, 2021		March 31, 2020
Revenues, net	\$ -	\$	-
Loss from operations	(2,831)		(1,131)
Net loss	\$ (2,831)	\$	(1,131)

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

	Iarch 31, 2021	cember 31, 2020
Current assets	\$ 6,013	\$ 9,074
Non current assets	44	45
Total assets	 6,057	 9,119
Total liabilities	1,328	1,666
Total stockholders equity	4,729	7,453
Total liabilities and stockholders' equity	\$ 6,057	\$ 9,119

# NOTE 6. RESTRICTED CASH

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

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

# NOTE 7. INVENTORIES

Inventories are comprised of finished compounded formulations, over-the-counter and prescription retail pharmacy products, commercial pharmaceutical products, related laboratory supplies and active pharmaceutical ingredients. The composition of inventories as of March 31, 2021 and December 31, 2020 was as follows:

	Marc	ch 31, 2021	Decen	nber 31, 2020
Raw materials	\$	2,512	\$	2,501
Work in progress		3		17
Finished goods		1,981		1,444
Total inventories	\$	4,496	\$	3,962

# NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	March 3	1, 2021	Dece	mber 31, 2020
Prepaid insurance	\$	171	\$	160
Other prepaid expenses		399		401
Deposits and other current assets		193		190
Total prepaid expenses and other current assets	\$	763	\$	751

# NOTE 9. PROPERTY, PLANT AND EQUIPMENT

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

	Mar	March 31, 2021		ember 31, 2020
Property, plant and equipment, net:				
Computer software and hardware	\$	1,900	\$	1,707
Furniture and equipment		422		418
Lab and pharmacy equipment		3,436		3,426
Leasehold improvements		5,725		5,720
		11,483		11,271
Accumulated depreciation and amortization		(7,283)		(6,818)
	\$	4,200	\$	4,453

For the three months ended March 31, 2021 and 2020, depreciation and amortization related to the property, plant and equipment was \$464 and \$448, respectively.



# NOTE 10. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at March 31, 2021 consisted of the following:

	Amortization periods (in years)	 Cost	 imulated rtization	Impa	irment	Ne	et carrying value
Patents	17-19 years	\$ 532	\$ (54)	\$	-	\$	478
Licenses	20 years	50	(6)		-		44
Trademarks	Indefinite	357	-		-		357
Customer relationships	3-15 years	1,519	(487)		-		1,032
Trade name	5 years	5	(5)		-		-
Non-competition clause	3-4 years	50	(50)		-		-
State pharmacy licenses	25 years	8	(7)		-		1
		\$ 2,521	\$ (609)	\$	_	\$	1,912

Amortization expense for intangible assets for the three months ended March 31, 2021 and 2020 was as follows:

	 For the Three Marc	 s Ended	
	 2021	2020	
Patents	\$ 6	\$	11
Licenses	1		1
Customer relationships	33		33
Trade name	-		-
State pharmacy licenses	-		-
	\$ 40	\$	45

Estimated future amortization expense for the Company's intangible assets at March 31, 2021 is as follows:

Remainder of 2021	\$ 149
2022	188
2023	188
2024	161
2025	148
Thereafter	 721
	\$ 1,555

# NOTE 11. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	March 31, 2021		December 31, 2020	
Accounts payable	\$	4,941	\$	3,645
Other accrued expenses		49		49
Accrued interest		186		238
Accrued exit fee for note payable		800		800
Total accounts payable and accrued expenses		5,976		4,732
Less: Current portion		(5,176)		(3,932)
Non-current total accrued expenses	\$	800	\$	800

## NOTE 12. DEBT

#### SWK Senior Note - 2017

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

Subsequent to March 31, 2021, the Company completed an offering of unsecured senior notes in the aggregate principal amount of \$55,000 and used a portion of the proceeds to pay off all outstanding obligations and indebtedness related to the SWK Loan (see Note 17 for additional information).

Interest expense related to the SWK Loan Agreement, as amended, amounted to \$509 and \$560 for the three months ended March 31, 2021 and 2020, respectively, and included amortization of debt issuance costs and discount of \$96 and \$160 for the three months ended March 31, 2021 and 2020, respectively.

#### Paycheck Protection Program Loan

In April 2020, the Company entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the "PPP Loan") in the principal amount of \$1,967 and received cash proceeds of the same amount, pursuant to the Paycheck Protection Program (the "PPP") under the Federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted March 27, 2020. The PPP is administered by the U.S. Small Business Administration (the "SBA"). On March 30, 2021, the Company received a notice of forgiveness of the full balance of the PPP Loan, including all accrued interest, in accordance with the terms and conditions of the CARES Act. Related to the forgiveness, the Company recorded a gain on the forgiveness of debt for the loan balance of \$1,967 in the accompanying condensed consolidated statement of operations for the period ended March 31, 2021.

At March 31, 2021, future minimum payments under the Company's debt were as follows:

	А	mount
Remainder of 2021	\$	3,395
2022		3,966
2023		9,511
Total minimum payments		16,872
Less: amount representing interest		(2,511)
Notes payable, gross		14,361
Less: unamortized discount		(706)
Notes payable		13,655
Less: current portion, net of unamortized discount		(2,659)
Note payable, net of current portion and unamortized debt discount	\$	10,996

# NOTE 13. LEASES

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

- An operating lease for 10,200 square feet of office space in San Diego, California that expires in December 2021, with an option to extend the term for a five-year period;
- An operating lease for 26,400 square feet of lab, warehouse and office space in Ledgewood, New Jersey that expires in July 2026, with an option to extend the term for two additional five-year periods. This includes an amendment that was made effective July 2020 that extended the term of the original lease and added 1,400 of additional square footage to the lease; and
- An operating lease for 5,500 square feet of office space in Nashville, Tennessee that expires in December 2024, with an option to extend the term for two additional five-year periods.

Future lease payments under operating leases as of March 31, 2021 were as follows:

	Opera	ting Leases
Remainder of 2021	\$	766
2022		1,038
2023		1,064
2024		1,090
2025		916
Thereafter		5,141
Total minimum lease payments		10,015
Less: amount representing interest payments		(2,922)
Total operating lease liabilities		7,093
Less: current portion, operating lease liabilities		(597)
Operating lease liabilities, net of current portion	\$	6,496

At March 31, 2021, the weighted-average discount rate and the weighted-average remaining lease term for the operating leases held by the Company were 6.33% and 11.02 years, respectively.

During the three months ended March 31, 2021 and 2020, cash paid for amounts included for the operating lease liabilities was \$251 and \$271, respectively, and the Company recorded operating lease expense of \$261 and \$278, respectively, included in selling, general and administrative expenses.

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

Future lease payments under the non-cancelable finance lease as of March 31, 2021 were as follows:

	Finance Leases	
Remainder of 2021	\$	7
2022		9
2023		9
2024		1
Total minimum lease payments		26
Less: amount representing interest payments		(2)
Present value of future minimum lease payments		24
Less: current portion, finance lease obligation		(8)
Finance lease obligation, net of current portion	\$	16

At March 31, 2021, the weighted average incremental borrowing rate and the weighted average remaining lease term for the finance lease held by the Company were 6.36% and 2.83 years, respectively.

For the three months ended March 31, 2021, depreciation expense related to the equipment held under the finance lease obligation was \$2.

For the three months ended March 31, 2021, cash paid and expense recognized for interest expense related to the finance lease obligation was \$1.

# NOTE 14. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

## **Common Stock**

During the three months ended March 31, 2021, the Company issued 11,301 shares of its common stock upon the exercise of options to purchase 11,301 shares of common stock, with exercise prices ranging between \$1.70 to \$3.96 per share and received net proceeds of \$27.

During the three months ended March 31, 2021, the Company issued 200,000 shares of its common stock to Mark L. Baum, its CEO, related to the vesting of 200,000 performance-based restricted stock units.

During the three months ended March 31, 2021, the Company issued 22,500 shares of common stock to Andrew R. Boll, its CFO, related to the vesting of 30,000 performance-based restricted stock units. The Company withheld issuance of 7,500 shares of common stock to Mr. Boll for payroll tax purposes valued at \$57.

During the three months ended March 31, 2021, 22,755 shares of the Company's common stock underlying RSUs issued to directors vested, but the issuance and delivery of these shares are deferred until the director resigns.

# **Preferred Stock**

At March 31, 2021 and 2020, the Company had 5,000,000 shares of preferred stock, \$0.001 par value, authorized and no shares of preferred stock issued and outstanding.

Subsequent to March 31, 2021, the Company sold 440,000 shares of Series B Cumulative Preferred Stock for gross proceeds of \$11,000 (see Note 17 for additional information).

## **Stock Option Plan**

On September 17, 2007, the Company's Board of Directors and stockholders adopted the Company's 2007 Incentive Stock and Awards Plan, which was subsequently amended on November 5, 2008, February 26, 2012, July 18, 2012, May 2, 2013 and September 27, 2013 (as amended, the "2007 Plan"). The 2007 Plan reached its term in September 2017, and we can no longer issue additional awards under this plan, however, options previously issued under the 2007 Plan will remain outstanding until they are exercised, reach their maturity or are otherwise cancelled/forfeited. On June 13, 2017, the Company's Board of Directors and stockholders adopted the Company's 2017 Incentive Stock and Awards Plan (the "2017 Plan" together with the 2007 Plan, the "Plans"). As of March 31, 2021, the 2017 Plan provides for the issuance of a maximum of 2,000,000 shares of the Company's common stock. The purpose of the Plans are to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in the Company's development and financial success. Under the Plans, the Company is authorized to issue incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-qualified stock options, restricted stock units and restricted stock. The Plans are administered by the Compensation Committee of the Company's Board of Directors. The Company had 4,077 shares available for future issuances under the 2017 Plan at March 31, 2021.

# Stock Options

A summary of stock option activity under the Plans for the three months ended March 31, 2021 is as follows:

	Number of Shares	Weighted Avg. Exercise Price		0 0		0 0		0 0		0 0		0 0		Exercise Price		Weighted Avg. Remaining Contractual Life	Aggregate trinsic Value
Options outstanding - January 1, 2021	3,030,033	\$	5.43														
Options granted	67,000	\$	8.07														
Options exercised	(11,301)	\$	2.42														
Options cancelled/forfeited	(28,195)	\$	5.45														
Options outstanding - March 31, 2021	3,057,537	\$	5.50	5.54	\$ 5,287												
Options exercisable	2,169,441	\$	4.85	5.04	\$ 4,944												
Options vested and expected to vest	2,968,979	\$	5.45	5.50	\$ 5,254												

The aggregate intrinsic value in the table above represents the total pre-tax amount of the proceeds, net of exercise price, which would have been received by option holders if all option holders had exercised and immediately sold all options with an exercise price lower than the market price on March 31, 2021, based on the closing price of the Company's common stock of \$6.75 on that date.

During the three months ended March 31, 2021, the Company granted stock options to certain employees and a consultant. The stock options were granted with an exercise price equal to the current market price of the Company's common stock, as reported by the securities exchange on which the common stock was then listed, at the grant date and have contractual terms of 10 years. Vesting terms for options granted to employees and consultants during the three months ended March 31, 2021 were as follows: 25% of the shares subject to the option vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the shares subject to the option vest and become exercisable quarterly in equal installments thereafter over three years. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plans) and in the event of certain modifications to the option award agreement.

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

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

	 2021
Weighted-average fair value of options granted	\$ 4.96
Expected terms (in years)	6.11
Expected volatility	69%
Risk-free interest rate	0.39-0.45%
Dividend yield	-



The following table summarizes information about stock options outstanding and exercisable at March 31, 2021:

	0	Options Outstanding		Options E	xercisable																				
		Weighted																							
		Average																							
	Nh	Remaining	Weighted		0		0		0		0		0		0		0		0		0		Normhan		eighted
Dange of Everycics Drives	Number	Contractual Life in Years	Average		Average Exercise Price		Number Exercisable		verage cise Price																
Range of Exercise Prices	Outstanding	Life in rears	Exe	rcise Price	Exercisable	Exer	cise Price																		
\$1.47 - \$2.60	760,318	5.38	\$	2.06	750,557	\$	2.06																		
\$2.76 - \$4.66	513,628	5.51	\$	3.98	442,498	\$	3.97																		
\$5.49 - \$6.36	470,350	6.84	\$	6.12	320,023	\$	6.13																		
\$6.64 - \$8.99	1,313,241	5.18	\$	7.86	656,363	\$	7.99																		
\$1.47 - \$8.99	3,057,537	5.54	\$	5.50	2,169,441	\$	4.85																		

As of March 31, 2021, there was approximately \$2,582 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 4.59 years. The stock-based compensation for all stock options was \$452 and \$263 during the three months ended March 31, 2021 and 2020, respectively.

The intrinsic value of options exercised during the three months ended March 31, 2021 was \$63.

# Restricted Stock Units

RSU awards are granted subject to certain vesting requirements and other restrictions, including performance and market-based vesting criteria. The grant date fair value of the RSUs, which has been determined based upon the market value of the Company's common stock on the grant date, is expensed over the vesting period of the RSUs.

During the three months ended March 31, 2021, 300,000 RSUs with a fair market value of \$2,670 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.

A summary of the Company's RSU activity and related information for the three months ended March 31, 2021 is as follows:

		Weighted A Grant Da	te Fair
	Number of RSUs	Valu	ie
RSUs unvested - January 1, 2021	1,601,509	\$	3.14
RSUs granted	300,000	\$	8.90
RSUs vested	(252,755)	\$	2.38
RSUs cancelled/forfeited	-		-
RSUs unvested at March 31, 2021	1,648,754	\$	4.30

As of March 31, 2021, the total unrecognized compensation expense related to unvested RSUs was approximately \$3,687, which is expected to be recognized over a weighted-average period of 0.82 years, based on estimated and actual vesting schedules of the applicable RSUs. The stock-based compensation for RSUs during the three months ended March 31, 2021 and 2020 was \$346 and \$259, respectively.

# Warrants

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



A summary of warrant activity for the three months ended March 31, 2021 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weigl	nted Avg. Exercise Price
Warrants outstanding - January 1, 2021	780,386	\$	2.12
Granted	-		-
Exercised	-		-
Expired	-		-
Warrants outstanding and exercisable - March 31, 2021	780,386	\$	2.12
Weighted average remaining contractual life of the outstanding warrants in years - March			
31, 2021	3.28		

Warrants outstanding and exercisable as of March 31, 2021 are as follows:

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

#### Subsidiary Stock-Based Transactions

The Company recognized \$57 in stock-based compensation expense related to subsidiary stock options during the three months ended March 31, 2021.

# **Stock-Based Compensation Summary**

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

	For the Three Months Ended March 31,					
		2021		2020		
Employees - selling, general and administrative	\$	755	\$	436		
Directors - selling, general and administrative		100		97		
Total	\$	855	\$	533		

#### NOTE 15. COMMITMENTS AND CONTINGENCIES

#### Legal

# Novel Drug Solutions et al.

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA (collectively "NDS") filed a lawsuit against the Company in the U.S. District Court of Delaware asserting claims for breach of contract. The claims stem from an asset purchase agreement between the Company and NDS entered into in 2013. In July 2019, NDS filed a second amended complaint which added a claim related to its purported termination of the APA. In October 2019, NDS voluntarily dismissed all claims related to breach of contract, leaving only claims related to the scope of the post-termination obligations to be litigated. On October 29, 2020, at a hearing on the various dispositive motions before it, the Court found that there were triable issues of fact and reopened discovery for limited purposes. NDS is seeking unspecified damages, interest, attorney's fees and other costs. The Company believes the claims are meritless and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend against these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation and it could result in substantial costs, losses and a diversion of management's resources and attention, which could harm the Company's business and the value of its common stock.

# **Product and Professional Liability**

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

# John Erick et al.

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

## General and Other

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

# Indemnities

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

# Klarity License Agreement – Related Party

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

Under the terms of the Klarity License Agreement, the Company is required to make royalty payments to Dr. Lindstrom ranging from 3% - 6% of net sales, dependent upon the final formulation of the Klarity Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including: (i) an initial payment of \$50 upon execution of the Klarity License Agreement, (ii) a second payment of \$50 following the first \$50 in net sales of the Klarity Product; and (iii) a final payment of \$50 following the first \$100 in net sales of the Klarity Product. All of the above referenced milestone payments are payable at the Company's election in cash or shares of the Company's restricted common stock. Payments totaling \$35 and \$55 were made during the three months ended March 31, 2021 and 2020, respectively. \$35 and \$29 was incurred as royalty expense during the three months ended March 31, 2021 and counts payable to Dr. Lindstrom.

# Injectable Asset Purchase Agreement – Related Party

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

Under the terms of the Lindstrom APA, the Company is required to make royalty payments to Dr. Lindstrom ranging from 2% to 3% of net sales, dependent upon the final formulation and patent protection of the Lindstrom Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including an initial payment of \$33 upon execution of the Lindstrom APA. Dr. Lindstrom was paid \$7 and \$7 in cash during the three months ended March 31, 2021 and 2020, respectively. The Company incurred \$7 and \$38 for royalty expenses related to the Lindstrom APA during the three months ended March 31, 2021 and 2020.

# **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<sup>®</sup> (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint will pay the Company a fee calculated based on the quarterly sales of DEXYCU in excess of predefined volumes to specific customers of the Company in the U.S. Under the terms of the Dexycu Agreement, the Company shall use commercially reasonable efforts to promote and market DEXYCU in the U.S.

Subject to early termination, the Dexycu Agreement expires on August 1, 2025, subject to specified notice periods and specified limitations, either party may terminate the Dexycu Agreement in the event of (i) uncured material breach by the other party or (ii) if DEXYCU ceases to have "pass-through" payment status. In addition, subject to certain limitations, the Company may terminate the Dexycu Agreement (i) for convenience subject to an extended specified notice period or (ii) in the event Eyepoint undergoes a change of control. Eyepoint may terminate the Dexycu Agreement, subject to specified notice periods and specified limitations, if the Company fails to achieve certain minimum sales levels during specified periods. During the three months ended March 31, 2021, the Company recorded \$485 in commission revenues related to the Dexycu Agreement.

# **Sales and Marketing Agreements**

The Company has entered various sales and marketing agreements with certain organizations, to provide exclusive and non-exclusive sales and marketing representation services to Harrow in select geographies in the U.S., in connection with the Company's ophthalmic pharmaceutical compounded formulations or related products.

Under the terms of the sales and marketing agreements, the Company is, generally, required to make commission payments equal to 10% - 14% of net sales for products above and beyond the initial existing sales amounts. In addition, the Company is required to make periodic milestone payments to certain organizations in shares of the Company's restricted common stock if net sales in the assigned territory reach certain future levels by the end of their terms, as applicable. \$0 and \$83 of stock-based payments were recorded and \$804 and \$603 were incurred under these agreements for commission expenses during the three months ended March 31, 2021 and 2020, respectively.

#### Asset Purchase, License and Related Agreements

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

In consideration for the acquisition of the intellectual property rights, the Company is obligated to make payments to the Inventors based on the completion of certain milestones, generally consisting of: (1) a payment payable within 30 days after the issuance of the first patent in the United States arising from the acquired intellectual property (if any); (2) a payment payable within 30 days after the Company files the first investigational new drug application ("IND") with the U.S. Food and Drug Administration ("FDA") for the first product arising from the acquired intellectual property (if any); (3) for certain of the Inventors, a payment payable within 30 days after the Company files the first 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 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. \$232 and \$144 were incurred under these agreements as royalty expenses and included in accounts payable at March 31, 2021 and 2020, respectively.

# NOTE 16. SEGMENT INFORMATION AND CONCENTRATIONS

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

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

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

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

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

Segment net revenues, segment operating expenses and segment contribution information consisted of the following for the three months ended March 31, 2021:

		For the Three Months Ended March 31, 2021								
	In	ıprimisRx	Pharmace Drug Devel			Total				
Net revenues	\$	15,443	\$	-	\$	15,443				
Cost of sales		(3,770)		-		(3,770)				
Gross profit		11,673		-		11,673				
Operating expenses:										
Selling, general and administrative		5,771		-		5,771				
Research and development		210		13		223				
Segment contribution		5,692		(13)		5,679				
Corporate						2,353				
Research and development						369				
Amortization						40				
Operating income					\$	2,917				

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

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the U.S.; therefore, total revenues are attributed to the U.S. All long-lived assets at March 31, 2021 and December 31, 2020 were located in the U.S.

### Concentrations

The Company sells its compounded formulations to a large number of customers. There were no customers who comprised more than 10% of the Company's total pharmacy sales for the three months ended March 31, 2021 and 2020.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 82% and 78% of active pharmaceutical ingredient purchases during the three months ended March 31, 2021 and 2020, respectively.

## NOTE 17. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to March 31, 2021 through the filing date of this Quarterly Report. Based on its evaluation, no events other than those described below need to be disclosed.

#### Vesting and Exercise of Equity Awards

In April 2021, the Company issued 515,871 shares of its common stock to Mark L. Baum, its Chief Executive Officer, upon the vesting of 850,000 performance-based restricted stock units. The Company withheld issuance of 334,129 shares of common stock valued at \$2,760 for payroll tax purposes.

In April 2021, the Company issued 77,668 shares of common stock to Andrew R. Boll, its Chief Financial Officer, upon the vesting of 127,500 performance-based restricted stock units. The Company withheld issuance of 49,832 shares of common stock valued at \$411 for payroll tax purposes.

In April 2021, the Company issued 5,000 shares of its common stock upon the exercise of options to purchase 5,000 shares of common stock, with an exercise price of \$4.29 per share, and received net proceeds of \$21.

## Sale of Eton Stock

In April 2021, the Company closed the underwritten public offering of 1,518,000 shares of its Eton common stock at a public offering price of \$7.00 per share (the "Eton Stock Sale"). The gross proceeds to the Company from the Eton Stock Sale were \$10,626, before deducting underwriting discounts and commissions and other offering expenses payable by the Company. Following such sale, the Company owns 1,982,000 shares of Eton common stock, which represented approximately 8.1% of the equity and voting interests issued and outstanding of Eton as of April 12, 2021.

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

#### 8.625% Senior Notes Due 2026

In April 2021, we closed an offering of \$50,000 aggregate principal amount of 8.625% Senior Notes due 2026 (the "Notes") and in May 2021, the underwriters exercised their option to purchase an additional \$5,000 aggregate principal amount of the Notes (\$55,000 in total). 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 the rate of 8.625% per annum. Interest on the Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, commencing on July 31, 2021. The Notes will mature on April 30, 2026. Prior to February 1, 2026, 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 for cash in whole or in part at any time at our option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption date, interest will cease to accrue on the redeemed Notes.

## SWK Loan Repayment

In April 2021, the Company paid \$15,540 related to all outstanding obligations to SWK under the SWK Loan, including outstanding principal, accrued interest, accrued exit fee and related expenses.

# Series B Cumulative Preferred Stock

In May 2021, the Company issued 440,000 shares of the Company's Series B Cumulative Preferred Stock, par value \$0.001 per share and liquidation preference of \$25.00 per share (the "Series B Preferred Stock"), for a net purchase price of approximately \$10,670. The Series B Preferred Stock is not convertible into our common stock, has no voting rights, except as required by Delaware law, and is redeemable by the Company at any time. Holders of Series B Preferred Stock, when and as authorized by the Company's Board of Directors, are entitled to cumulative cash dividends at the rate of 9.50% of the \$25.00 liquidation preference per year (equivalent to \$2.375 per share per year); provided, however, that for each thirty (30) day period following May 5, 2021, the dividend rate shall be increased in increments of fifty (50) basis points, and effective September 30, 2021, the dividend rate shall be set at 12%, and for each thirty (30) day period thereafter, the dividend rate shall be increased in increments of ne hundred (100) basis points except as otherwise limited by applicable law. Dividends will be payable quarterly in arrears, on or about the 15th of January, April, July and October, beginning on or about July 15, 2021. In the event of any liquidation, dissolution or winding-up of the Company, the holders of the Series B Preferred Stock will have preference to holders of our common stock at \$25.00 per share plus any accrued and unpaid dividends (whether or not authorized or declared).



#### Mayfield Pharmaceuticals MAY-66 License Termination

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

## Mayfield Pharmaceuticals MAY-44 APA Termination

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

# Stowe License Termination

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

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

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

The information contained in this Quarterly Report is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Quarterly Report and in our other reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and subsequent reports, which discuss our business in greater detail. As used in this discussion and analysis, unless the context indicates otherwise, the terms the "Company", "Harrow" "we", "us" and "our" refer to Harrow Health, Inc. and its consolidated subsidiaries, consisting of Park Compounding, Inc., ImprimisRx, LLC, ImprimisRx NJ, LLC dba ImprimisRx, Imprimis NJOF, LLC, Radley Pharmaceuticals, Inc., Mayfield Pharmaceuticals, Inc., and Stowe Pharmaceuticals, Inc. In this discussion and analysis, we refer to our consolidated subsidiaries ImprimisRx, LLC, ImprimisRx NJ, LLC and Imprimis NJOF, LLC collectively as "ImprimisRx."

In addition to historical information, the following discussion contains forward-looking statements regarding future events and our future performance. In some cases, you can identify forward-looking statements by terminology such as "will", "may", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "forecasts", "potential" or "continue" or the negative of these terms or other comparable terminology. All statements made in this Quarterly Report other than statements of historical fact are forward-looking statements. These forward-looking statements involve risks and uncertainties and reflect only our current views, expectations and assumptions with respect to future events and our future performance. If risks or uncertainties materialize or assumptions prove incorrect, actual results or events could differ materially from those expressed or implied by such forward-looking statements. Risks that could cause actual results to differ from those expressed or implied by the forward-looking statements we make include, among others, risks related to: the impact of the COVID-19 pandemic on our financial condition, liquidity or results of operations; our ability to successfully implement our business plan, develop and commercialize our proprietary formulations in a timely manner or at all, identify and acquire additional proprietary formulations, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our previous acquisitions and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions; regulatory and legal risks and uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general; physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally; our limited operating history; and the other risks and uncertainties described under the heading "Risk Factors" in Part II, Item 1A of this Quarterly Report and in our other filings with the 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 forwardlooking statement for any reason.

#### Overview

Our business specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace through our subsidiaries and deconsolidated companies. We own and operate one of the nation's leading ophthalmology pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, we also have equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Ophthalmics, Inc. ("Surface"), and Melt Pharmaceuticals, Inc. ("Melt"), all companies that began as subsidiaries of Harrow. In 2020, Harrow created Visionology, Inc. ("Visionology") and will launch an online eye health platform business in certain regions. We also own royalty rights in various drug candidates being developed by Surface and Melt.



## ImprimisRx

ImprimisRx is our ophthalmology focused prescription pharmaceutical business. We offer to over 10,000 physician customers and their patients critical medicines to meet their needs that are unmet by commercially available drugs. We make our formulations available at prices that are, in most cases, lower than non-customized commercial drugs. Our current ophthalmology formulary includes over twenty compounded formulations, many of which are patented or patent-pending, and are customizable for the specific needs of a patient. Some examples of our compounded medications are various combinations of drugs formulated into one bottle and numerous preservative free formulations. Depending on the formulation, the regulations of a specific state and ultimately the needs of the patient, ImprimisRx products may be dispensed as patient-specific medications from our 503A pharmacy, or for in-office use, made according to current good manufacturing practices (or cGMPs) or other FDA-guidance documents, in our FDA-registered New Jersey outsourcing facility ("NJOF").

# Visionology

Visionology, a direct-to-consumer online eye health platform, leverages our experience in the ophthalmic pharmaceutical business as well as our relationships with eyecare professionals across the United States. We expect to launch a proof-of-concept model for Visionology within a certain region of the U.S., and if successful, will expand the launch on a nationwide basis later in 2021.

# **Pharmaceutical Compounding Businesses**

# Pharmaceutical Compounding

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

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

#### **Our Compounding Facilities**

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

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

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

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

# **Pharmaceutical Development Businesses**

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

In 2018 and 2019, we formed and created subsidiaries named Radley Pharmaceuticals, Inc. ("Radley"), Mayfield Pharmaceuticals, Inc. ("Mayfield"), and Stowe Pharmaceuticals, Inc. ("Stowe"). In 2020, we halted nearly all operating activities related to these subsidiaries to invest resources in other areas and may not restart any or all activities related to these businesses.

#### **De-Consolidated Businesses (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.

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

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

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

In 2018, Surface closed on an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements. We own 3,500,000 shares of Surface which was approximately 30% of the equity and voting interests as of March 31, 2021. Harrow owns mid-single digit royalty rights on net sales of SURF-100, SURF-200 and SURF-201. We expect Surface to complete another round of financing within the next six months.

## 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"), and Harrow assigned to Melt the underlying intellectual property for Melt's current pipeline, including its lead drug candidate MELT-100. The core intellectual property Melt owns is a patented series of combination non-opioid sedation drug formulations that we estimate to have multitudinous applications. MELT-100 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-100. In February 2021, Melt announced data from, and the successful completion of, its phase 1 study. Melt expects to begin its phase 2 study for MELT-100 in the second half of 2021.

In January 2019, Melt closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Melt from our consolidated financial statements. We own 3,500,000 shares of Melt common stock, which was approximately 44% of the equity and voting interests issued and outstanding of as of March 31, 2021. We expect Melt to complete another round of financing within the next six months. Pursuant to 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 MELT-100, 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-100. If approved, we do not expect a cessation of compounding like products to have a material impact on our operations and financial performance.

# Eton Pharmaceuticals, Inc.

Eton is a commercial-stage pharmaceutical company focused on developing and commercializing innovative drug products. Its pipeline includes several products and drug candidates in various stages of development across a variety of dosage forms. In May 2017, Eton closed an offering of its Series A Preferred Stock and we lost our controlling interest in it. In November 2018, Eton completed an initial public offering of its common stock. At that time, we gave up our controlling interest and deconsolidated Eton from our consolidated financial statements. As of the date of this Quarterly Report and following our April 2021 sale, we own 1,982,000 shares of Eton common stock. We owned less than 20% of the equity and voting interests issued and outstanding of Eton as of March 31, 2021.

## **Factors Affecting Our Performance**

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

#### **Reimbursement Options**

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



#### **COVID-19** Pandemic

A novel strain of coronavirus was first identified in Wuhan, China in December 2019. The disease caused by it, COVID-19, was declared a global pandemic by the World Health Organization in March 2020. On March 18, 2020, CMS released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. In addition to limiting elective medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendation, and created significant volatility in financial markets. In May 2020 and the following months, U.S. states and geographies began easing restrictions associated with the COVID-19 pandemic including those restrictions related to elective procedures. We have since seen sales of our products return to near historical norms and trends as restrictions associated with elective procedures and the COVID-19 pandemic have continued to ease.

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

## **Recent Developments**

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

#### **PPP** Loan

In April 2020, we entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the "PPP Loan") in the principal amount of \$1,967,000 and received cash proceeds of the same amount, pursuant to the Paycheck Protection Program (the "PPP") under the Federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted March 27, 2020. The PPP is administered by the U.S. Small Business Administration. On March 30, 2021, the Company received a notice of forgiveness of the full balance of the PPP Loan, including all accrued interest, in accordance with the terms and conditions of the CARES Act and accordingly recognized a gain on forgiveness of debt of \$1,967,000.

#### **Eton Stock Sale**

In April 2021, we closed an underwritten public offering of 1,518,000 shares of our Eton common stock at a public offering price of \$7.00 per share (the "Eton Stock Sale"). The gross proceeds to us from the Eton Stock Sale were \$10,626,000 before deducting underwriting discounts and commissions and other offering expenses payable by the Company. Following such sale, we own 1,982,000 shares of Eton common stock, which represented approximately 8.1% of the equity interests issued and outstanding of Eton as of April 12, 2021.

As part of the Eton Stock Sale, we also agreed, for a period of 180 days, not to conduct any further sales of shares of its common stock of Eton or otherwise dispose of, directly or indirectly, any common stock of Eton (or any securities convertible into, or exercisable or exchangeable for, the common stock of Eton). The Company expects to use the net proceeds from the Eton Stock Sale for general corporate purposes, including funding future strategic product acquisitions and related investments, making capital expenditures and funding working capital.

#### 8.625% Senior Notes Due 2026

In April 2021, we closed an offering of \$50,000,000 aggregate principal amount of 8.625% Senior Notes due 2026 (the "Notes") and in May 2021, the underwriters exercised their option to purchase an additional \$5,000,000 aggregate principal amount of the Notes (\$55,000,000 in total). The Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of our other existing and future senior unsecured and unsubordinated indebtedness. The Notes are effectively subordinated in right of payment to all of our existing and future secured indebtedness and structurally subordinated to all existing and future indebtedness of the Company's subsidiaries, including trade payables. The Notes bear interest at the rate of 8.625% per annum. Interest on the Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, commencing on July 31, 2021. The Notes will mature on April 30, 2026.

Prior to February 1, 2026, we may, at our option, redeem the Notes, in whole at any time or in part from time to time, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus a make-whole amount, if any, plus accrued and unpaid interest to, but excluding, the date of redemption. We may redeem the Notes for cash in whole or in part at any time at our option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption. On and after any redemption date, interest will cease to accrue on the redeemed Notes. The Company expects to use the net proceeds from the Notes for general corporate purposes, including funding future strategic product acquisitions and related investments, making capital expenditures and funding working capital.



# Series B Cumulative Preferred Stock

On May 5, 2021, we issued 440,000 shares of Series B Cumulative Preferred Stock ("Series B Preferred Stock") for gross proceeds of \$11,000. The Series B Preferred Stock is not convertible into our common stock, has no voting rights, except as required by Delaware law, and is redeemable by us at any time. Holders of Series B Preferred Stock, when and as authorized by the our Board of Directors, are entitled to cumulative cash dividends at the rate of 9.50% of the \$25.00 liquidation preference per year (equivalent to \$2.375 per share per year); provided, however, that for each thirty (30) day period following May 5, 2021, the dividend rate shall be increased in increments of fifty (50) basis points, and effective September 30, 2021, the dividend rate shall be set at 12%, and for each thirty (30) day period thereafter, the dividend rate shall be increased in increments of one hundred (100) basis points except as otherwise limited by applicable law. Dividends will be payable quarterly in arrears, on or about the 15th of January, April, July and October, beginning on or about July 15, 2021. In the event of any liquidation, dissolution or winding-up of the Company, the holders of the Series B Preferred Stock will have preference to holders of our common stock at \$25.00 per share plus any accrued and unpaid dividends (whether authorized or declared). The Company expects to use the net proceeds from the Series B Preferred Stock for general corporate purposes, including funding future strategic product acquisitions and related investments, making capital expenditures and funding working capital.

#### Mayfield Pharmaceuticals MAY-66 License Termination

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

#### Mayfield Pharmaceuticals MAY-44 APA Termination

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

#### **Stowe License Termination**

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

#### **Results of Operations**

The following period-to-period comparisons of our financial results for the three months ended March 31, 2021 and 2020, are not necessarily indicative of results for the current period or any future period. *Revenues* 

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

The following presents our revenues for the three months ended March 31, 2021 and 2020:

	For the Three Months Ended March 31,					\$		
		2021		2020		Variance		
Product sales, net	\$	14,948,000	\$	11,810,000	\$	3,138,000		
Other revenues		495,000		7,000		488,000		
Total revenues	\$	15,443,000	\$	11,817,000	\$	3,626,000		

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

# Cost of Sales

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

The following presents our cost of sales for the three months ended March 31, 2021 and 2020:

	For the Three Months Ended						
		March 31,				\$	
		2021	2019		Varia		
Cost of sales	\$	3,770,000	\$	3,626,000	\$	144,000	

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

#### Gross Profit and Margin

	I	For the Three Months Ended March 31,				\$	
		2021	2021 2020		Variance		
Gross Profit	\$	11,673,000	\$	8,191,000	\$	3,482,000	
Gross Margin		75.6%		69.3 <sup>%</sup>		6.3%	

The increase in gross margin between periods is largely attributable to increased unit volumes sold, efficiencies in our production process, including increased batch sizes and improved utilization of capacities as a result of increased output.

# Selling, General and Administrative Expenses

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

The following presents our selling, general and administrative expenses for the three months ended March 31, 2021 and 2020:

	For the Three Months Ended					
	March 31,				\$	
	202	L	2020	Variance		
Selling, general and administrative	\$ 8,1	54,000 \$	8,416,000	\$	(252,000)	

The decrease in selling, general and administrative expenses between periods was mostly attributable to a slight decrease in sales and marketing expenses associated with our pharmacy operations.

#### Research and Development Expenses

Our research and development 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, and other costs related to the clinical development of our assets.

The following presents our research and development expenses for the three months ended March 31, 2021 and 2020:

	F	For the Three Months Ended March 31,				\$	
		2021		2020 Varia		/ariance	
Research and development	\$	592,000	\$	403,000	\$	189,000	

The increase in research and development expenses between periods was primarily attributable to formulation development studies for new ophthalmic formulations and clinical programs related to our drug development segment during the three months ended March 31, 2021.

#### Interest Expense, net

Interest expense, net was \$513,000 for the three months ended March 31, 2021, compared to \$560,000 for the same period last year. The decrease during the period ended March 31, 2021 compared to the same period in 2020 was primarily due to interest expense recognition related to a decrease in the outstanding principal amount of our debt obligations.

# Investment Loss from Melt

During the three months ended March 31, 2021 and 2020, we recorded a net loss of \$470,000 and \$546,000, respectively, related to our share of losses in Melt.

# Investment Loss from Surface

During the three months ended March 31, 2021 and 2020, we recorded a loss of \$849,000 and \$339,000, respectively, for our share of losses based on our ownership of Surface.

# Investment Loss from Eton

We recorded an unrealized loss of \$2,835,000 and \$10,850,000 related to the change in fair market value of Eton's common stock for the three months ended March 31, 2021 and 2020, respectively.

## Gain on Forgiveness of Debt

During the three months ended March 31, 2021, we recorded gain on forgiveness of debt of \$1,967,000, related to the forgiveness of our PPP Loan.

#### Net Income (Loss)

The following table presents our net income (loss) and per share net income (loss) for the three months ended March 31, 2021 and 2020:

	For the Three Months Ended March 31,				
	 2021	2020			
Net income (loss) attributable to Harrow Health, Inc.	\$ 217,000	\$	(12,907,000)		
Net income (loss) per share, basic	\$ 0.01	\$	(0.50)		
Net income (loss) per share, diluted	\$ 0.01	\$	(0.50)		

## **Financial Information About Segments and Geographic Areas**

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

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

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

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



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

See Note 16 to our condensed consolidated financial statements included in this Quarterly Report for more information about our reportable segments.

# Liquidity and Capital Resources

# Liquidity

Our cash on hand (including restricted cash) at March 31, 2021 was \$6,504,000, compared to \$4,301,000 at December 31, 2020.

As of the date of this Quarterly Report, we believe that cash and cash equivalents of \$6,304,000 and restricted investments of \$200,000, totaling approximately \$6,504,000 at March 31, 2021, along with gross proceeds received from the Eton Stock Sale of \$10,626,000, \$55,000,000 from the issuance of the Notes and \$11,000,000 from the issuance of our Series B Cumulative Preferred Stock will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. In addition, we may consider the sale of certain assets including, but not limited to, part of, or all of, our ownership interest in Eton, Surface, Melt, and/or any of our consolidated subsidiaries. However, our plans for this period may change, our estimates of our operating expenses, capital expenditures and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies, 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 earlier than we expect to support our operations.

We expect to use our current cash position and funds generated from our operations and any financing to pursue our business plan, which includes developing and commercializing compounded formulations and technologies, integrating and developing our 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 Three months Ended March 31,				
		2021		2020		
Net cash provided by (used in):			_			
Operating activities	\$	3,208,000	\$	(550,000)		
Investing activities		(224,000)		(273,000)		
Financing activities		(781,000)		(2,000)		
Net change in cash and cash equivalents		2,203,000	_	(825,000)		
Cash, cash equivalents and restricted cash at beginning of the period		4,301,000		4,949,000		
Cash, cash equivalents and restricted cash at end of the period	\$	6,504,000	\$	4,124,000		

# **Operating Activities**

Net cash provided by operating activities was \$3,208,000 compared to net cash used in operating activities of \$550,000 during the same period in the prior year. The increase in net cash provided by operating activities during the periods was mainly attributed to the increase in revenues.

## Investing Activities

Net cash used in investing activities during the three months ended March 31, 2021 and 2020 was \$(224,000) and \$(273,000), respectively. Cash used in investing activities in 2021 and 2020 was primarily associated with equipment and software purchases and upgrades along with investments in our intellectual property portfolio.



# Financing Activities

Net cash used in financing activities during the three months ended March 31, 2021 and 2020 was \$(781,000) and \$(2,000), respectively. Cash used in financing activities during the three months ended March 31, 2021 was related to principal payments on our SWK loan.

## Sources of Capital

Our principal sources of cash consist of cash provided by operating activities from our pharmaceutical compounding business, in addition to proceeds received subsequent to March 31, 2021 from the sale of the Notes, Series B Preferred Stock and sale of Eton Stock. We may also sell some or all of our ownership interests in Surface, Melt or our other subsidiaries, along with the remaining portion of our Eton common stock.

The changing trends and overall economic outlook in light of the COVID-19 pandemic, including the historical interim stay-at-home orders and bans on elective surgeries, created uncertainty surrounding our operating outlook and may impact our future operating results if there is a rise in COVID-19 related cases in the US. 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 expens

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

#### **Recently Issued and Adopted Accounting Pronouncements**

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

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

# **Item 4. Controls and Procedures**

## **Evaluation of Disclosure Controls and Procedures**

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

Under the supervision and with the participation of our principal executive officer and principal financial officer, our management conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act, as they existed on March 31, 2021. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of March 31, 2021, the end of the period covered by this report.

## Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended March 31, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal control over financial reporting due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 pandemic on our internal controls to minimize the impact on their design and operating effectiveness.

# PART II OTHER INFORMATION

# **Item 1. Legal Proceedings**

See Note 15 to our condensed consolidated financial statements included in this Quarterly Report for information on various legal proceedings, which is incorporated into this Item by reference.

### Item 1A. Risk Factors

You should carefully consider the following risk factors in addition to the other information contained in this Quarterly Report. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks. You should consider all of the factors described in this section when evaluating our business as well as the risk factors and the other information in our Annual Report on Form 10-K for the year ended December 31, 2020, including our audited financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations". If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investments. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

### Risks Related to Our Financial Position, Need for Additional Capital and Senior Notes

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

In April and May 2021, we issued \$55,000,000 of 8.625% senior notes due 2026. We may incur additional indebtedness in the future. Our ability to make scheduled payments on our indebtedness depends on our future performance and ability to raise additional capital, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional capital through equity sales or incurrence of additional debt on terms that may be onerous or highly dilutive to our stockholders. Our ability to engage in any of these activities would depend on the capital markets and our financial condition at such time, and we may not be able to do so when needed, on desirable terms or at all, which could result in a default on our debt obligations. Additionally, our debt instruments contain or, from time to time, may contain various restrictive covenants, including, among others, our obligation to deliver certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without prior consent, to dispose of certain of our assets, incur certain additional indebtedness, enter into certain merger, acquisition or change of control transactions, pay certain dividends or distributions on or repurchase any of our capital stock or incur any lien or other encumbrance on our assets, subject to certain permitted exceptions. Any failure by us to comply with any of these covenants, subject to certain cure periods, or to make all payments under the debt instruments when due, would cause us to be in default under the applicable debt instrument. In the event of any such default, lenders may be able to foreclose on our assets that secure the debt or declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially cau

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

We only recently started generating cash from operations, but we do not currently earn sufficient revenues to support our operations. We may need significant additional capital to execute our business plan and fund our proposed business operations. Additionally, our plans may change or the estimates of our operating expenses and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies or other strategic transactions that involve large expenditures, or we may experience growth more quickly or on a larger scale than we expect, any of which may result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing earlier than we expect to support our operations.



We have raised over \$65,000,000 in gross proceeds through equity and debt financings in April and May 2021. We may seek to obtain additional capital through equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or other financing transactions. If we issue additional equity or debt securities to raise funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration and licensing arrangements or sales of assets, we may have to relinquish potentially valuable rights to our drug candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If we raise funds by incurring additional debt, we may be required to pay significant interest expenses and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as options, convertible notes and warrants, which would adversely impact our financial results.

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

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

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

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

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



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

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

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

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

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

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

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

### We may issue additional notes.

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

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

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

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

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

### **Risks Related to the Series B Preferred Stock**

# We have the right to issue shares of preferred stock without obtaining stockholder approval. The Series B Preferred Stock has, and any preferred stock issued in the future may have, rights, preferences and privileges superior to those of our common stock.

We are authorized to issue 5,000,000 shares of "blank check" preferred stock, with such rights, preferences and privileges as may be determined from time to time by our Board of Directors. On May 5, 2021, we issued 440,000 shares of Series B Cumulative Preferred Stock. Such shares have rights, preferences and privileges superior to those of our common stock. Our Board of Directors is empowered, without stockholder approval, to issue additional preferred stock at any time in one or more series and to fix the dividend rights, dissolution or liquidation preferences, redemption prices, conversion rights, voting rights and other rights, preferences and privileges for any series of our preferred stock that may be issued. The issuance of shares of such preferred stock, depending on the rights, preferences and privileges attributable to the preferred stock, could reduce the voting rights and powers of our common stockholders and the portion of our assets allocated for distribution to holders of our Series B Preferred Stock and to common stockholders in a liquidation event, and could also result in dilution to the book value per share of our stock. The preferred stock could also be utilized, under certain circumstances, as a method for raising additional capital or discouraging, delaying or preventing a change in control of our Company.

### We cannot assure that quarterly dividends on, or any other payments in respect of, the Series B Preferred Stock will be made timely or at all.

We cannot assure that we will be able to pay quarterly dividends on the Series B Preferred Stock or redeem the Series B Preferred Stock, if we wanted to do so. Quarterly dividends on our Series B Preferred Stock will be paid from funds legally available for such purpose when, as and if declared by our Board of Directors. Certain factors may influence our decision, or adversely affect our ability, to pay dividends on, or make other payments in respect of, our Series B Preferred Stock, including, among other things, the amount of our available cash or other liquid assets; our ability to service and refinance our current and future indebtedness; restrictions imposed by our existing, or any future, credit facilities or other debt instruments; and limitations on cash payments to stockholders under Delaware law, including limitations that require dividend payments be made out of surplus or, subject to certain limitations, out of net profits for the then-current or preceding year in the event there is no surplus.

# We may seek to redeem the Series B Preferred Stock given the increasing dividends to which such shares are entitled. We may not have sufficient capital to redeem the Series B Preferred Stock if, and when, we seek to redeem the stock.

The shares of Series B Preferred Stock have no maturity or mandatory redemption date. However, the dividend rate for such shares increases over time and, as a result, we may seek to redeem the Series B Preferred Stock. By their terms, the Series B Preferred Stock may be redeemed by us at our option either in whole or in part at any time. Any decision we may make at any time regarding whether to redeem the Series B Preferred Stock will depend upon a wide variety of factors, including our evaluation of our capital position, our capital requirements and general market conditions at that time. However, investors should not assume that we will redeem the Series B Preferred Stock at any particular time, or at all.

# The Series B Preferred Stock ranks junior to all of the Company's indebtedness and other liabilities and are effectively junior to all indebtedness and other liabilities of the Company's subsidiaries.

In the event of a bankruptcy, liquidation, dissolution or winding-up of the affairs of the Company, the Company's assets will be available to pay obligations on the Series B Preferred Stock only after all of the Company's indebtedness and other liabilities have been paid. The rights of holders of the Series B Preferred Stock to participate in the distribution of the Company's assets will rank junior to the prior claims of the Company's current and future creditors and any future series or class of preferred stock the Company may issue that ranks senior to the Series B Preferred Stock. In addition, the Series B Preferred Stock effectively ranks junior to all existing and future indebtedness and other liabilities of (as well as any preferred equity interests held by others in) the Company's existing subsidiaries and any future subsidiaries. The Company's existing subsidiaries are, and any future subsidiaries would be, separate legal entities and have no legal obligation to pay any amounts to the Company in respect of dividends due on the Series B Preferred Stock then outstanding. The Company and its subsidiaries have incurred and may in the future incur substantial amounts of debt and other obligations that will rank senior to the Series B Preferred Stock. The Company may incur additional indebtedness and become more highly leveraged in the future, which could harm the Company's financial position and potentially limit cash available to pay dividends. As a result, the Company may not have sufficient funds remaining to satisfy its dividend obligations relating to the Series B Preferred Stock if the Company incurs additional indebtedness. If the Company decides to issue debt or senior equity securities in the future, it is possible that these securities will be governed by an indenture or other instrument containing covenants restricting the Company's operating flexibility.



### **Risks Related to Regulatory Approval and Other Legal Compliance Matters**

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

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

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

On July 30, 2020 and separately on March 24, 2021, the FDA issued public notices for comments related to certain bulk drug substances to be removed from the 503B Bulk's List (or Category 1 List). Included in these notices for comment were certain bulk drug substances which we currently use in some of our compounded products. In the event one or more of these bulk substances are ultimately removed from the Category 1 List, we intend to utilize commercially available versions of these substances or similar active pharmaceutical ingredients as replacements of the bulk powders contained in our sterile products. In addition, nothing in the FDA's notice affects the dispensing of bulk powder-containing products from our 503A pharmacy. Nonetheless, if all or some of the bulk drug substances we use are removed from the 503B Bulk's List, this may result in a disruption in our operations, revenues and cash flows.

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

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

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### 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**

### Mayfield Pharmaceuticals MAY-66 License Termination

On May 10, 2021, Mayfield terminated the License Agreement (the "TGV License") with TGV-Health, LLC and affiliated entities (collectively, "TGV"), pursuant to which it acquired intellectual property rights for use in the women's health field, related to Mayfield's proprietary drug candidate MAY-66. Concurrent with the termination, TGV returned to Mayfield 300,000 shares of Mayfield's common stock, constituting all of the equity held by TGV. Mayfield has no outstanding or remaining obligations under the TGV License.

### Mayfield Pharmaceuticals MAY-44 APA Termination

On May 10, 2021, Mayfield and Harrow terminated their asset purchase agreement dated January 2020 for intellectual property rights associated with Mayfield's drug candidate MAY-44 with Elle Pharmaceutical LLC (the "MAY-44 APA"). As part of the termination, Mayfield re-acquired 350,000 shares of its common stock from Elle for \$350. Mayfield has no outstanding or remaining obligations related to the MAY-44 APA.

#### Stowe License Termination

On May 10, 2021, Stowe terminated the License Agreement (the "Stowe License") with TGV, pursuant to which it acquired intellectual property rights for use in the ophthalmic field, related to Stowe's proprietary drug candidate STE-006. Concurrent with the termination, TGV returned to Stowe 1,750,000 shares of Stowe's common stock, constituting all of the equity held by TGV. Stowe has no outstanding or remaining obligations under the Stowe License.

## Item 6. Exhibits

Exhibit Number	Description
3.1	<u>Certificate of Designation designating the Series B Cumulative Preferred Stock of the Company (incorporated herein by reference to Exhibit 3.1</u> to the Current Report on Form 8-K of the Company filed with the SEC on May 5, 2021).
4.1	Indenture, dated as of April 20, 2021, by and between the Company and U.S. Bank National Association, as Trustee (incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed with the SEC on April 20, 2021).
4.2	<u>First Supplemental Indenture, dated as of April 20, 2021, by and between the Company and U.S. Bank National Association, as Trustee</u> (incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed with the SEC on April 20, 2021).
4.3	Form of 8.625% Senior Note due 2026 (included in Exhibit 4.2).
10.1	Securities Purchase Agreement, dated as of May 5, 2021, by and between the Company and B. Riley Securities, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the SEC on May 5, 2021).
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.
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- **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 March 31, 2021, 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.

Dated: May 11, 2021

# Harrow Health, Inc.

By: /s/ Mark L. Baum

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

By: /s/ Andrew R. Boll

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

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

I, Mark L. Baum, certify that:

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

Date: May 11, 2021

/s/ Mark L. Baum

Mark L. Baum Chief Executive Officer Principal Executive Officer

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

I, Andrew R. Boll, certify that:

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

Date: May 11, 2021

/s/ Andrew R. Boll

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

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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned hereby certifies in his capacity as the specified officer of Harrow Health, Inc. (the "Company"), that, to the best of his knowledge, the Quarterly Report of the Company on Form 10-Q for the fiscal quarter ended March 31, 2021 fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented in the financial statements included in such report.

Date: May 11, 2021

/s/ Mark L. Baum

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

Date: May 11, 2021

/s/ Andrew R. Boll

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

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