UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to

Commission File Number 001-40353

IMPEL NEUROPHARMA, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-3058238**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

201 Elliott Avenue West, Suite 260
Seattle, WA 98119
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (206) 568-1466

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The number of shares of Registrant's Common Stock outstanding as of November 10, 2021 was 23,039,393.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical facts, including statements concerning our business strategy and plans, future operating results and financial position, as well as our objectives and expectations for our future operations, are forward-looking statements.

In some cases, you can identify forward-looking statements by such terminology as “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect” and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements about:

- our ability to successfully formulate and execute on our commercialization strategy for Trudhesa;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any approved product;
- the timing or likelihood of regulatory filings and approvals;
- the size and growth potential of the market for Trudhesa and the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- the success, cost and timing of our development activities, preclinical studies and clinical trials;
- the number, size and design of clinical trials that regulatory authorities may require to obtain marketing approval;
- our plans relating to the future development and manufacturing of our product candidates, including plans for future development of our POD devices and plans to address additional indications for which we may pursue regulatory approval;
- future agreements with third parties in connection with preclinical and clinical development as well as the manufacture and commercialization of our product candidates, if approved for commercial use;
- our ability to attract customers for any approved products;
- the effect of litigation, complaints or adverse publicity on our business;
- our ability to establish and expand our sales force to address effectively the new indications, geographies and types of organizations we intend to target;
- our ability to forecast and maintain an adequate rate of revenue growth and appropriately plan our expenses;
- our liquidity and working capital requirements;
- our ability to attract and retain qualified employees and key personnel;
- our ability to protect and enhance our brand and intellectual property;
- the costs related to defending intellectual property infringement and other claims;
- privacy, data security, and data protection laws, actual or perceived privacy or data breaches or other data security incidents, or the loss of data;
- future regulatory, judicial, and legislative changes in our industry;
- future arrangements with, or investments in, other entities or associations, products, services or technologies;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and the increased expenses and administrative workload associated with being a public company.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, prospects, and financial needs. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We disclaim any intention or obligation to publicly update or revise any forward-looking statements for any reason or to conform such statements to actual results or revised expectations, except as required by law.

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In this Quarterly Report on Form 10-Q, "we," "our," "us," "Impel" and the "Company" refer to Impel Neuropharma, Inc. and its consolidated subsidiary. Impel, Impel Neuropharma, Inc., the Impel logo and other trade names, trademarks or service marks of Impel are the property of Impel Neuropharma, Inc. This report contains references to our trademarks and to trademarks belonging to other entities. Trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

IMPEL NEUROPHARMA, INC.
Condensed Consolidated Balance Sheet
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 111,289	$ 7,095
Trade receivables, net	981	—
Inventory	1,548	—
Prepaid expenses and other current assets	4,385	1,077
Total current assets	118,203	8,172
Property and equipment, net	3,278	3,700
Other assets	—	187
Total assets	$ 121,481	$ 12,059
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 8,700	$ 4,314
Accrued liabilities	6,692	3,173
Current portion of term debt	—	417
Common stock warrant liabilities	918	—
Redeemable convertible preferred stock warrant liabilities	—	2,622
Total current liabilities	16,310	10,526
Convertible notes at fair value	—	—
Long-term debt	29,285	7,994
Total liabilities	45,595	18,520
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock, $0.001 par value; — and 204,198,489 shares authorized at September 30, 2021 and December 31, 2020 respectively; — and 202,009,981 shares issued and outstanding at September 30, 2021 and December 31, 2020 respectively; aggregate liquidation preference of $128,922 at December 31, 2020	—	127,039
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 and — shares authorized at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value; 300,000,000 and 266,833,885 shares authorized at September 30, 2021 and December 31, 2020, respectively; 23,037,298 and 755,478 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	23	—
Additional paid-in capital	265,919	4,762
Accumulated deficit	(190,056)	(138,262)
Total stockholders' equity (deficit)	75,886	(133,500)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 121,481	$ 12,059

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

IMPEL NEUROPHARMA, INC.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue, net	$ 91	$ —	$ 91	$ —
Cost of goods sold	250	—	250	—
Gross profit	(159)	—	(159)	—
Operating expenses:				
Research and development	5,929	6,133	16,103	19,524
Selling, general and administrative	16,338	2,866	30,971	12,240
Total operating expenses	22,267	8,999	47,074	31,764
Loss from operations	(22,426)	(8,999)	(47,233)	(31,764)
Other (expense) income, net	(2,595)	(93)	(4,561)	(9)
Loss before income taxes	(25,021)	(9,092)	(51,794)	(31,773)
Provision (benefit) for income taxes	—	1	—	1
Net loss and comprehensive loss	$ (25,021)	$ (9,093)	$ (51,794)	$ (31,774)
Accretion on redeemable convertible preferred stock	—	130	129	386
Net loss attributable to common stockholders	$ (25,021)	$ (9,223)	$ (51,923)	$ (32,160)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.24)	$ (15.56)	$ (4.42)	$ (73.16)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	20,150,990	592,550	11,746,923	439,575

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

IMPEL NEUROPHARMA, INC.
Condensed Consolidated Statement of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance — December 31, 2020	202,009,981	$ 127,039	755,478	$ —	$ 4,762	$ (138,262)	$ (133,500)
Accretion to redemption value on redeemable convertible preferred stock	—	129	—	—	(129)	—	(129)
Stock-based compensation expense	—	—	—	—	493	—	493
Issuance of common stock upon the exercise of stock options	—	—	8,095	—	18	—	18
Net loss and comprehensive loss	—	—	—	—	—	(11,291)	(11,291)
Balance — March 31, 2021	202,009,981	$ 127,168	763,573	$ —	$ 5,144	$ (149,553)	$ (144,409)
Proceeds from initial public offering, net of underwriters' discounts and commissions of $5.6 million and issuance costs of $2.4 million	—	—	5,333,334	5	71,992	—	71,997
Issuance of common stock upon exercise of warrants for cash	—	—	23,887	—	377	—	377
Issuance of common stock upon net exercise of warrants upon initial public offering		—	37,628	—	734	—	734
Issuance of common stock upon exchange of Avenue warrant	—	—	107,663	—	1,763	—	1,763
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	(202,009,981)	(127,168)	12,605,800	13	127,155	—	127,168
Conversion of convertible notes into common stock at initial public offering	—	—	559,585	1	8,392	—	8,393
Stock-based compensation expense	—	—	—		556	—	556
Issuance of common stock upon the exercise of stock options	—	—	39,444	—	201	—	201
Net loss and comprehensive loss	—	-	-	-	-	(15,482)	(15,482)
Balance — June 30, 2021	—	$ —	19,470,914	$ 19	$ 216,314	$ (165,035)	$ 51,298
Proceeds from follow-on public offering, net of underwriters' discounts and commissions of $2.8 million and issuance costs of $0.6 million	—	—	3,450,000	4	48,312	—	48,316
Stock-based compensation expense	—	—	—		978	—	978
Issuance of common stock upon the exercise of stock options	—	—	116,384	—	315	—	315
Net loss and comprehensive loss	—	—	—	—	—	(25,021)	(25,021)
Balance — September 30, 2021	—	$ —	23,037,298	$ 23	$ 265,919	$ (190,056)	$ 75,886

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

IMPEL NEUROPHARMA, INC.
Condensed Consolidated Statement of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance — December 31, 2019	201,335,862	$ 125,647	360,115	$ —	$ 760	$ (92,464)	$ (91,704)
Accretion to redemption value on redeemable convertible preferred stock	—	129	—	—	(128)	—	(128)
Stock-based compensation expense	—	—	—	—	298	—	298
Issuance of common stock upon the exercise of stock options	—	—	3,569	—	8	—	8
Net loss and comprehensive loss						(9,759)	(9,759)
Balance — March 31, 2020	201,335,862	$ 125,776	363,684	$ —	$ 938	$ (102,223)	(101,285)
Accretion to redemption value on redeemable convertible preferred stock	—	127	—	—	(128)	—	(128)
Stock-based compensation expense	—	—	—	—	2,485	—	2,485
Issuance of Series A-2 redeemable convertible preferred stock upon the exercise of preferred warrants	36,029	18	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	(12,922)	(12,922)
Balance —June 30, 2020	201,371,891	$ 125,921	363,684	$ —	$ 3,295	$ (115,145)	$ (111,850)
Accretion to redemption value on redeemable convertible preferred stock	—	130	—	—	(130)	—	(130)
Stock-based compensation expense	—	—	—	—	432	—	432
Issuance of common stock upon the exercise of stock options	—	—	326,117	—	687	—	687
Issuance of Series A-2 redeemable convertible preferred stock upon the exercise of preferred warrants	46,769	58	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock upon the exercise of preferred warrants	378,111	18	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	(9,093)	(9,093)
Balance —September 30, 2020	201,796,771	$ 126,127	689,801	$ —	$ 4,284	$ (124,238)	$ (119,954)

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

IMPEL NEUROPHARMA, INC.
Condensed Consolidated Statement of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (51,794)	$ (31,774)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	775	814
Stock-based compensation	2,027	3,215
Change in fair value of warrant liabilities	222	(46)
Change in fair value of convertible notes	839	—
Loss on early extinguishment of debt	1,993	—
Amortization of debt discount	549	—
Write-down of inventory to net realizable value	98	—
Noncash interest	54	—
Changes in operating assets and liabilities:		
Accounts receivable	(981)	—
Inventory	(1,646)	—
Prepaid expenses and other current assets	(3,308)	900
Other assets	187	(191)
Accounts payable	4,296	(752)
Accrued liabilities	3,519	(1,053)
Net cash used in operating activities	$ (43,170)	$ (28,887)
Cash flows from investing activities:		
Purchases of property and equipment	(264)	(893)
Net cash used in investing activities	$ (264)	$ (893)
Cash flows from financing activities:		
Proceeds from initial public offering, net of issuance costs	71,997	—
Proceeds from follow-on public offering, net of issuance costs	48,316	—
Proceeds from issuance of long-term debt	19,083	—
Proceeds from issuance of convertible notes	7,500	—
Proceeds from exercise of redeemable convertible preferred stock warrants	197	372
Proceeds from issuance of common stock upon exercise of stock options	535	695
Proceeds from Paycheck Protection Program	—	1,100
Repayment of Paycheck Protection Program	—	(1,100)
Net cash provided by financing activities	$ 147,628	$ 1,067
Net increase (decrease) in cash	104,194	(28,713)
Cash — Beginning of period	7,095	37,001
Cash — End of period	$ 111,289	$ 8,288
Supplemental disclosures of cash flow information:		
Accretion to redemption value on redeemable convertible preferred stock	$ 129	$ 386
Conversion of redeemable convertible preferred stock upon initial public offering	127,168	—
Issuance of common stock upon exchange / exercise of redeemable convertible preferred stock warrants upon initial public offering	2,677	—
Conversion of convertible notes into common stock upon initial public offering	8,393	—
Recognition of fair value of warrant liabilities issued in connection with issuance of debt	751	—
Reclass of redeemable convertible preferred stock warrant liability to redeemable convertible preferred stock upon exercise of the warrants	-	306
Purchase of property and equipment included in accounts payable and accrued liabilities	90	898

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

IMPEL NEUROPHARMA, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Description of Business

Impel Neuropharma, Inc. (“the Company”, "we", and "our"), is a late-stage pharmaceutical company focused on the development and commercialization of transformative therapies for patients suffering from diseases with high unmet medical needs, with an initial focus on diseases of the central nervous system, or CNS. The Company's lead product, Trudhesa™ (dihydroergotamine mesylate) Nasal Spray was approved by the U.S. Food and Drug Administration ("FDA") on September 3, 2021. Using the Company’s proprietary Precision Olfactory Delivery (POD®) technology, Trudhesa™ gently delivers dihydroergotamine mesylate (DHE), a proven, well-established therapeutic, quickly to the bloodstream through the vascular-rich upper nasal space.

The Company’s strategy is to pair its POD®, upper nasal delivery technology with well-understood therapeutics or other therapeutics where rapid vascular absorption is preferred to drive therapeutic benefit, improve patient outcomes, reduce drug development risk and expand the commercial opportunity within its target diseases. The Company was incorporated under the laws of the State of Delaware on July 24, 2008, maintains its headquarters and principal operations in Seattle, Washington, and performs certain of its research and development activities in Australia.

Initial Public Offering

On April 22, 2021, the Company’s Registration Statement on Form S-1 relating to its initial public offering, or IPO, was declared effective by the Securities and Exchange Commission, or the SEC, and the shares of its common stock began trading on the Nasdaq Global Select Market on April 23, 2021. The IPO closed on April 27, 2021, pursuant to which the Company issued and sold 5,333,334 shares of its common stock at a public offering price of $15.00 per share. The Company received net proceeds of approximately $72.0 million from the IPO, after deducting underwriting discounts and commissions of $5.6 million and offering costs of $2.4 million. Prior to the completion of the IPO, all shares of redeemable convertible preferred stock then outstanding were converted into 12,605,800 shares of common stock. In addition, the warrant held by Avenue Venture Opportunities Fund, L.P., or Avenue, was exchanged for 107,663 shares of common stock and warrants to purchase 1,987,348 shares of redeemable convertible preferred stock were cash exercised or automatically net exercised into an aggregate of 61,515 shares of common stock. The convertible notes issued in March 2021 for an aggregate principal amount of $7.5 million (see Note 6) were also converted into 559,585 shares of common stock at a 10% discount of the IPO price.

Follow-on Public Offering

In September 2021, the Company completed a follow-on public offering of its common stock, pursuant to which the Company issued and sold 3,450,000 shares of its common stock (which included 450,000 shares that were offered and sold pursuant to the full exercise of the underwriters’ option to purchase additional shares) at a public offering price of $15.00 per share. Including the option exercise, the Company received net proceeds of approximately $48.3 million after deducting underwriting discounts and commissions of $2.8 million and offering costs of $0.6 million.

Reverse Stock Split

In April 2021, the Company’s board of directors and stockholders approved an amendment to the Company’s certificate of incorporation to effect a reverse split of shares of the Company’s common stock on an one-for-16.37332 basis, which was effected on April 16, 2021 (the “Reverse Stock Split”). The number of authorized shares and the par values of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. In connection with the Reverse Stock Split, the conversion ratio for the Company’s outstanding redeemable convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. All references to common stock and options to purchase common stock share data, per share data and related information contained in the condensed consolidated financial statements have been retroactively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Liquidity and Capital Resources

From the Company’s inception through September 30, 2021, it raised an aggregate of $292.8 million in proceeds from the IPO, follow-on public offering, sale and issuance of redeemable convertible preferred stock, convertible notes, debt and warrants. The Company had a cash and cash equivalents balance of $111.3 million as of September 30, 2021. Based upon the Company’s current operating plan, it estimates that its cash and cash equivalents as of September 30, 2021, are together sufficient for the Company to fund operating, investing, and financing cash flow needs for at least one year from the issuance date of these interim financial statements. The

Company may be required to raise additional capital to meet working capital needs associated with commercialization and research and development activities. If sufficient funds on acceptable terms are not available when needed, the Company could be required to reduce operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs or planned product launch plans. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Company's ability to achieve its intended business objectives.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The condensed consolidated financial statements include the operations of Impel Neuropharma, Inc., and its wholly owned Australian subsidiary. All intercompany balances and transactions have been eliminated upon consolidation.

The condensed consolidated balance sheet as of September 30, 2021, the condensed consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the three and nine months ended September 30, 2021 and 2020 are unaudited. These unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's consolidated financial position as of September 30, 2021 and its results of operations and cash flows for the three and nine months ended September 30, 2021 and 2020. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the three and nine month periods are also unaudited. The results of operations for the three months and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the prospectus dated April 23, 2021 that forms a part of the Company's Registration Statement on Form S-1 (File No. 333-254999), as filed with the SEC pursuant to Rule 424(b)(4) promulgated under the Securities Act of 1933, as amended.

Reclassifications

We have reclassified prior period financial statements to conform to the current period presentation. During the nine months ended 2021, we reclassified certain amounts previously recorded as general and administrative expense to research and development expense.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, management evaluates such estimates and assumptions for continued reasonableness. In particular, management makes estimates with respect to revenue recognition, inventory valuation, the fair values of common stock (prior to the Company's IPO), common stock and redeemable convertible preferred stock warrant liabilities, stock-based compensation expense, convertible debt and income taxes. Appropriate adjustments, if any, to the estimates used are made prospectively based upon such periodic evaluation. Actual results could differ from those estimates.

Segments

The Company's chief operating decision maker is its Chief Executive Officer. The Chief Executive Officer reviews financial information on an aggregate basis for the purposes of evaluating financial performance and allocating the Company's resources. Accordingly, the Company has determined that it operates in one segment.

Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. At September 30, 2021 and December 31, 2020, cash consisted of cash in bank deposits held at financial institutions.

Accounts Receivable, net

The Company's trade accounts receivable consists of amounts due from specialty pharmacies in the U.S. net of distribution service fees, prompt pay discounts and other adjustments. The Company's contracts with customers have standard payment terms that generally require payment within 45 days. The Company analyzes accounts that are past due for collectability, and periodically evaluates the creditworthiness of its customers. As of September 30, 2021, we determined an allowance for doubtful accounts was not required based upon our review of contractual payment terms and individual customer circumstances. As of September 30, 2021, two customers accounted for 100% of the accounts receivable balance, with each of these individual customers ranging from 48% to 52% of the accounts receivable balance. The Company had no accounts receivable related to product sales in 2020.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services.

Product Revenue, Net

Subsequent to its regulatory approval in the U.S. in September 2021, the Company began to sell Trudhesa in the U.S. The product is distributed through an exclusive third-party logistics, or 3PL, distribution agent that does not take title to the product. The 3PL distributes Trudhesa to the Company's customers, a specialty pharmacy and a specialty distributor (collectively referred to as "customers"), who then distribute the product to health care providers and patients. In our exclusive distribution agreement with the 3PL company, the Company acts as principal because we retain control of the product.

Revenue from product sales is recognized when the customer obtains control of our product, which occurs upon transfer of title to the customer. We classify payments to customers or other parties in the distribution channel for services that are distinct and priced at fair value as selling, general and administrative expenses in our condensed consolidated statements of operations. Payments to customers or other parties in the distribution channel that do not meet those criteria are classified as a reduction of revenue, as discussed further below. Taxes collected from the customer relating to product sales and remitted to governmental authorities are excluded from revenue. Because our payment terms are generally forty-five days, we conclude there is not a significant financing component because the period between the transfer of a promised good or service to the customer and when the customer pays for that good or service will be one year or less. The Company expenses incremental costs of obtaining a contract as and when incurred since the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, or the transaction price, which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, co-pay assistance, chargebacks, rebates and other allowances that are offered within contracts between us and our customer, health care providers and other indirect customers relating to the sale of Trudhesa. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following are the components of variable consideration related to product revenue:

Product Returns: Our customer has limited return rights related to the product's damage or defect. The Company estimates the amount of product sales that may be returned and records the estimate as a reduction of revenue and a refund liability in the period the related product revenue is recognized. Based on the distribution model for Trudhesa and the price of Trudhesa, the Company believes there will be minimal returns.

Other incentives: Other incentives include co-payment assistance the Company provides to patients with commercial insurance that have coverage and reside in states that allow co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue. The estimate is recorded as a reduction of revenue in the same period the related revenue is recognized.

Managed care rebates: The Company maybe be subject to rebates with certain commercial payers in the future. We will record these rebates as an accrual on our condensed consolidated balance sheet in the same period we recognize the related revenue. We will estimate our managed care rebates based on our estimated payer mix and the applicable contractual rebate rate.

Chargebacks: The Company estimates obligations resulting from contractual commitments with the government and other entities to sell products to qualified healthcare providers and patients at prices lower than the list prices charged to our customer. The government and other entities charge us for the difference between what they pay for the product and the selling price to our customer. The Company records reserves for these chargebacks related to product sold to our customer during the reporting period, as well as our estimate of product that remains in the distribution channel at the end of the reporting period that we expect will be sold to qualified healthcare providers and patients in future periods. As of September 30, 2021, Impel did not enter into any contracts with government entities and other entities that are eligible for chargebacks.

Government rebates: The Company is subject to discount obligations under government programs, including Medicaid programs, Medicare and Tricare in the U.S. We estimate Medicaid, Medicare and Tricare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payer mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability that is included in accrued expenses on our consolidated balance sheet. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. On a quarterly basis, we update our estimates and record any adjustments in the period that we identify the adjustments.

Inventory

Prior to receiving approval from the FDA in September 2021 to sell Trudhesa in the U.S., the Company expensed all costs incurred related to the manufacture of Trudhesa as research and development expense because of the inherent risks associated with the development of a drug candidate, the uncertainty about the regulatory approval process and the lack of history for the Company of regulatory approval of drug candidates. Subsequent to receiving FDA approval in September 2021, the Company began to capitalize inventory related costs that were incurred subsequent to FDA approval. The Company values its inventories at the lower-of-cost or net realizable value and determines the cost of its inventories, which includes costs related to products held for sale in the ordinary course of business, products in process of production for such sale and items to be currently consumed in the production of goods to be available for sale, on a first-in, first-out (FIFO) basis. Due to the nature of the Company's supply chain process, inventory that is owned by the Company, is physically stored at third-party warehouses, logistics providers and contract manufacturers. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified. If they occur, such impairment charges are recorded as a component of cost of goods sold in the condensed consolidated statements of operations and comprehensive loss.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and overhead costs associated with Trudhesa. A portion of the costs of producing Trudhesa sold to date was expensed as research and development prior to the FDA approval of Trudhesa and, therefore, it is not reflected in the cost of goods sold.

Cost of goods sold for the three months ended September 30, 2021, included a charge of $0.1 million related to the write down of inventory to net realizable value in the condensed consolidated statements of operations and comprehensive loss.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash. The Company's cash is deposited with high credit quality financial institutions. At times such deposits may be in excess of the Federal Depository Insurance Corporation insured limits.

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active;

Level 3— Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in the accompanying consolidated balance sheets for cash, other current assets, accounts payable, and accrued liabilities approximate their fair values, due to their short-term nature. The estimated fair value of long-term debt as of September 30, 2021 approximated the principal amount outstanding, based on borrowing rates available to the Company for loans with similar terms and consideration of the Company's credit risk. As such, the Company's long-term debt was classified within Level 3 of the fair value hierarchy.

Convertible Notes

In March 2021, the Company issued convertible promissory notes to various investors for an aggregate amount of $7.5 million. As permitted under Accounting Standards Codification ("ASC") 825, Financial Instruments ("ASC 825"), the Company has elected the fair value option for recognition of the convertible notes. The Company elected the fair value option to allow the Company to eliminate the burden of complying with the requirements for derivative accounting. Under the fair value option, the convertible notes are remeasured at fair value in each reporting period until their conversion in April 2021, with changes in the fair value recognized in the Company's condensed consolidated statement of operations as other (expense) income, net. Accrued interest on the convertible notes is recorded in other (expense), net.

Research and Development Expense

Research and development costs are expensed as incurred and consist primarily of salaries, benefits and other staff-related costs, including associated stock-based compensation, laboratory supplies, nonclinical and clinical studies and trials and related clinical manufacturing costs, costs related to manufacturing preparation, fees paid to other entities that conduct certain research and development activities on the Company's behalf. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed. Such payments are evaluated for current or long-term classification based on when such services are expected to be received.

The Company considers regulatory approval of product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. The Company expenses manufacturing costs as incurred to research and development expense for product candidates prior to regulatory approval. If, and when, regulatory approval of a product is obtained, the Company begins capitalizing manufacturing costs related to the approved product into inventory.

Selling, General and Administrative Expense

Selling, general and administrative expenses are primarily comprised of compensation and benefits associated with sales and marketing, finance, human resources, legal, information technology and other administrative personnel, outside marketing, advertising and legal expenses and other general and administrative costs. The Company expenses the cost of advertising, including promotional expenses, as incurred. Advertising expenses were $4.6 million and $7.5 million for the three and nine months ended September 30, 2021, respectively.

Advance Payments and Accruals for Research and Development Services

As part of the process of preparing its condensed consolidated financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with its research and development efforts. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts.

The Company's objective is to reflect the appropriate research and development expenses in its condensed consolidated financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of its research and development efforts. The Company determines advance payments for research and development services and accrual estimates through discussion with applicable personnel and outside service providers as to the progress of clinical trials, or other services completed. The Company adjusts its rate of research and development expense recognition if actual results differ from its estimates. The Company makes estimates of its advance payments and accrued expenses as of each balance sheet date in its condensed consolidated financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. Through September 30, 2021, there had been no material adjustments to the Company's prior period estimates of advance payments and accruals for research and development expenses. The Company's research and development advance payments and accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Warrant Liabilities

The Company determines the accounting classification of warrants that are issued, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10 , Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, ("ASC 480-10"), and then in accordance with ASC 815-40, Derivatives and Hedging -- Contracts in Entity's Own Equity ("ASC 815-40"). Under ASC 480-10, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If the warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded as a component of other (expense) income, net in the accompanying condensed consolidated statements of operations. Equity classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Freestanding warrants to purchase shares of the Company's redeemable convertible preferred stock are accounted for as liabilities at fair value through the date of exercise, because the shares underlying the warrants contain contingent redemption features outside the control of the Company. The Company adjusted the liability for the final change in the fair value of these warrants immediately preceding their automatic exercise in connection with the IPO. Upon exercise, the corresponding liability was reclassified to additional paid-in capital.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for stock options and restricted stock unit awards on a straight-line basis over the requisite service period. The Company's stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes-Merton option pricing model. This model utilizes as inputs the estimated fair value of the underlying common stock at the measurement date, the estimated term of the stock options (weighted-average period of time that the options granted are expected to be outstanding), risk-free interest rates, expected dividends, and the expected volatility of the Company's common stock. The Company has elected to recognize forfeitures of share-based payment awards as they occur.

The Company recognizes stock-based compensation expense for stock options granted to non-employees based on the estimated fair value of the award as it is more readily measurable than the fair value of the services received.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company.

Comprehensive Loss

Comprehensive loss represents the change in the Company's stockholders' equity (deficit) from all sources other than investments by or distributions to stockholders. The Company has no items of other comprehensive loss; as such, net loss equals comprehensive loss.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-02, *Leases*, or Topic 842, which supersedes the guidance in former ASC 840, *Leases*. This standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for as a period cost. In May 2020, the FASB issued ASU No. 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*, which deferred the effective dates for non-public entities. Therefore, this standard is effective for annual reporting periods, and interim periods within those years, for public entities beginning after December 15, 2018 and for private entities beginning after December 15, 2021. As an Emerging Growth Company, we have elected to follow the private company adoption timeline for ASC 842. Originally, a modified retrospective transition approach was required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued guidance to permit an alternative transition method for Topic 842, which allows transition to the new lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Entities may elect to apply either approach. There are also a number of optional practical expedients that entities may elect to apply. The Company is currently assessing the impact of this standard on its condensed consolidated financial statements.

Recently Adopted Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, or ASU 2020-06, which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for the Company for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020 and adoption must be as of the beginning of the Company's annual fiscal year. The Company early adopted this standard on January 1, 2021 and the adoption of the standard did not have a significant impact on its consolidated financial statements.

3. Fair Value Measurements

The following table summarizes the fair value of the Company's financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$ 918	$ 918
Total financial liabilities	$ —	$ —	$ 918	$ 918

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Redeemable convertible preferred stock warrant liabilities	$ —	$ —	$ 2,622	$ 2,622
Total financial liabilities	$ —	$ —	$ 2,622	$ 2,622

The following table summarizes the change in the fair value of the common stock warrant liabilities for the nine months ended September 30, 2021 (in thousands):

Beginning balance as of December 31, 2020	$ —
Issuance of common stock warrants	751
Change in fair value	167
Ending balance as of September 30, 2021	$ 918

The following table summarizes the change in the fair value of the redeemable convertible preferred stock warrant liabilities for the nine months ended September 30, 2021 (in thousands):

Beginning balance as of December 31, 2020	$ 2,622
Changes in fair value	55
Settlement upon IPO	(2,677)
Ending balance as of September 30, 2021	$ —

The following table summarizes the change in the fair value of the convertible notes for the nine months ended September 30, 2021 (in thousands):

Beginning balance as of December 31, 2020	$ —
Issuance of convertible notes	7,500
Interest	54
Changes in fair value	839
Conversion upon IPO	(8,393)
Ending balance as of September 30, 2021	$ —

Fair values of the Company's common stock warrants, redeemable convertible preferred stock warrant liabilities and convertible notes are based on significant inputs not observed in the market, and thus represent a Level 3 measurement. Refer to Note 6 and Note 7 for the valuation techniques and assumptions used in estimating the fair value of the convertible notes and warrants, respectively.

4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Refundable clinical deposits	$ 217	$ 672
Tax refund receivable	293	229
Prepaid insurance	2,091	47
Other prepaids and current assets	1,784	129
Total prepaid expenses and other current assets	$ 4,385	$ 1,077

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued professional services	$ 1,771	$ 192
Accrued sales discounts and allowances	883	—
Accrued compensation	3,272	2,393
Accrued other liabilities	766	333
Accrued construction in progress	—	255
Total accrued liabilities	$ 6,692	$ 3,173

5. Commitments and Contingencies

Operating Leases

The Company leases office and laboratory space in Seattle, Washington.

In September 2017, the Company entered into a non-cancelable operating lease for 11,256 square feet of office and laboratory space. Rent is payable monthly, increasing by approximately 3% each year. As of September 30, 2021, the remaining future minimum lease payments were $0.7million through the expiration date of August 31, 2022.

Rent expense for the three months and nine months ended September 30, 2021 was $175,000 and $521,000, respectively and for the three and nine months ended September 30, 2020 was $158,000 and $458,000 respectively.

Legal Proceedings

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company intends to enter into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid.

COVID-19

In March 2020, the COVID-19 disease was declared a pandemic by the World Health Organization. Management continues to evaluate the potential impacts of the COVID-19 pandemic on the development of its product candidates, and business. The Company is working closely with its manufacturing vendors to maintain adequate product supply and with healthcare providers as future studies are planned to mitigate risk to patients while adhering to regulatory, institutional and government guidance and policies. The Company remains committed to its development plans and acknowledges the potential risk for delays in the product supply chain and in anticipated timelines for its preclinical studies and clinical trials.

6. Debt

Long-term debt consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Face value of term loans	$ 30,000	$ 10,000
Final payment	1,950	450
Unamortized debt discount associated with final payment, issuance date warrant fair value, and financing costs	(2,665)	(2,039)
Total debt, net	$ 29,285	$ 8,411
Less: short-term debt	—	417
Long-term debt	$ 29,285	$ 7,994

Oxford and Silicon Valley Bank Term Loan

On July 2, 2021, the Company entered into a loan and security agreement (the "Agreement") with Oxford Finance LLC ("Oxford"), as the collateral agent and a lender, and Silicon Valley Bank ("SVB" and, together with Oxford, the “Lenders”), as a lender, pursuant to which the Lenders have agreed to lend the Company up to an aggregate of $50.0 million in a series of term loans (the “Term Loan”). Upon entering into the Agreement, the Company borrowed $20.0 million from the Lenders (the “Term A Loan”), with approximately $10.8 million of such amount applied to the repayment of the outstanding principal, interest and final payment fees owed pursuant to the Company’s prior loan and security agreement with Avenue Venture Opportunities Fund, L.P., (“Avenue”). dated November 5, 2020.

Under the terms of the Agreement, the Company may, at its sole discretion, borrow from the Lenders up to an additional $10.0 million (the “Term B Loan”) upon the achievement by the Company of NDA approval from the FDA of TUDHESA, as determined by Oxford in its sole and absolute discretion (the “Term B Milestone Event”). On September 30, 2021, upon the occurrence of the Term B Milestone Event, the Company borrowed $10.0 million under the Term B Loan.

Under the terms of the Agreement, the Company may, at its sole discretion, borrow from the Lenders up to an additional $20.0 million (the “Term C Loan”) upon the achievement by the Company of net revenue for a trailing six (6) month period of at least $15.0 million, as determined by Oxford in its sole and absolute discretion (the “Term C Milestone Event”). The Company may draw the Term C Loan during the period commencing on the date of the occurrence of the Term C Milestone Event and ending on the earliest of (i) December 31, 2022 (ii) the sixtieth (60th) day following the occurrence of the Term C Milestone Event, and (iii) the occurrence of an event of default.

The outstanding loan balance accrues interest at the greater of (i) 7.95% or (ii) the sum of (a) the greater of (1) the thirty (30) day U.S. LIBOR or (2) 0.11%, plus (b) 7.84%. The Agreement provides for an interest-only period until September 1, 2023, followed by 35 equal monthly payments of principal and interest, if the Term C Milestone Event is not achieved by December 31, 2022. Following the Company’s achievement of the Term C Milestone Event by not later than December 31, 2022, the Term Loans will be interest-only through September 1, 2024, followed by 23 equal monthly payments of principal and interest.

All of the Term Loans mature on July 1, 2026 (the “Maturity Date”) and the Company has the option to prepay the outstanding balance prior to maturity, subject to a prepayment fee of 1.0% to 3.0% depending upon when the prepayment occurs. Upon repayment of the Term Loans, the Company is required to make a final payment fee to the Lenders equal to 6.5% of the original principal amount of the Term Loans funded which will be accrued by charges to interest expense over the term of the loans using the effective interest method.

The Term Loans are secured by all assets of the Company, other than its intellectual property. The Company has also agreed not to encumber its intellectual property assets, except as permitted by the Agreement.

The borrowings maybe subject to financial covenants if the Company draws down on Term C Loan commencing with the quarter ending March 31, 2023. The Agreement also includes subjective acceleration clauses which permit the lenders to accelerate the maturity date under certain circumstances, including, but not limited to, material adverse effects on a Company's financial status or otherwise. While the Company believes the acceleration of the due date may be reasonably possible, it is not probable and therefore, the debt is classified as a non-current liability in the accompanying balance sheet as of September 30, 2021. As of September 30, 2021, the Company is in compliance with all covenants in Agreement.

In connection with entering into the Agreement and borrowing the Term A Loan and Term B Loan, the Company issued warrants to purchase 71,522 and 23,166, shares of its common stock, respectively, (the "Warrants") to the Lenders at a per share exercisable price of $8.39 and $12.95, respectively, all with ten year terms. If the Company borrows additional Term Loans under the Agreement, the Company will be required to issue to the Lenders additional warrants exercisable for a number of shares of the Company's common stock equal to 3.0% of the total additional Term Loans funded by the Lenders divided by the lower of (x) the 10-trading day trailing average closing price prior to such Term Loan funding or (y) the closing price on the day prior to such Term Loan funding.

The Company recorded the Warrants as a debt discount, which is classified as a contra-liability against long-term debt on the condensed consolidated balance sheet, and is amortizing the balance over the life of the underlying debt. The offset to the contra-liability is recorded to Common Stock Warrant Liabilities on the condensed consolidated balance sheet as the Warrants do not meet the criteria for equity classification under ASC 815-40 and meet the definition of a derivative. The Company's Warrants are not indexed to the Company's common stock in the manner contemplated by ASC 815-40 because the warrant provides for an adjustment to the exercise price upon an acquisition. The Warrants were measured at fair value at inception and are subsequently remeasured at each reporting date with changes in fair value recognized as a component of other (expense) income, net in the condensed consolidated statement of operations and other comprehensive loss.

The Company determined the fair value of the Term A Loan and Term B Loan warrants at the date of issuance was $0.5 million and $0.2 million, respectively, using the Black-Scholes-Merton option pricing model based on significant unobservable inputs (Level 3). The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Assumptions used included an expected term of 10 years, stock volatility ranging from 73.0% to 78.6% and risk-free interest rates ranging from 1.44% to 1.52% during the three months ended September 30, 2021.

The Company incurred $0.1 million in debt issuance costs in connection with the closing of the Term A and Term B Loans. Debt issuance costs and discounts are presented in the consolidated balance sheet as a direct deduction from the associated liability and amortized to interest expense over the term of the related debt. Interest expense for the three and nine months ended September 30, 2021 was $0.5 million and is inclusive of non-cash amortization in the amount of $0.1 million related to the amortization of the debt issuance costs and accretion of final payment.

Avenue Term Loan

On November 5, 2020 the Company entered into a debt and equity financing agreement with Avenue. The agreement provided for a 36-month term loan of up to $20.0 million, of which $10.0 million ("Avenue Term Loan") was funded at close and (b) an additional $10.0 million was available at the Company's request until December 31, 2021, subject to (i) completion of an underwritten public offering with gross proceeds of at least $75.0 million, or a Qualified Offering, (ii) receipt of FDA approval of Trudhesa and (iii) approval by Avenue's investment committee. The term loan bears interest at the higher of the prime rate or 11%. In connection with the agreement, the Company granted Avenue warrants for the purchase of shares of 1,762,810 shares of Series D redeemable convertible preferred stock, as disclosed in Note 7.

On July 2, 2021, upon entering into the Agreement, the $10.8 million of outstanding principal, interest and final payment fees owed under the debt and equity financing agreement with Avenue was repaid by the Lenders. The Company evaluated whether the Oxford and SVB credit facility entered into in July 2021 represented a debt modification or extinguishment in accordance with ASC 470-50, Debt—Modifications and Extinguishments and determined that the existing Avenue Term Loan was extinguished as a result of the full repayment of the Avenue Term Loan and concurrent issuance of a new credit facility with new creditors, Oxford and SVB. The Company recorded a loss of $2.0 million on the early extinguishment of debt related to the unamortized debt discount associated with the fair value of the warrants, final payment fee, and unamortized debt issuance costs. The loss on early extinguishment was recognized as a component of other (expense) income, net in the condensed consolidated statement of operations and other comprehensive loss

Convertible Promissory Notes

In March 2021, the Company issued unsecured convertible promissory notes to various investors for an aggregate amount of $7.5 million which were accounted for at fair value. The notes bore interest at a rate of 5.0% per annum and mature on the earlier of (a) December 31, 2021 and (b) a change of control. The notes were automatically converted into shares of the Company's common stock upon the closing of the IPO in April 2021.

On March 31, 2021, the notes were remeasured to their settlement amount at the IPO date excluding accrued interest due to the proximity of the settlement date to the end of the reporting period. The loss on the increase in fair value on the convertible notes totaled $839,000 from their issuance until settlement and is classified as other (expense) income, net in the accompanying condensed consolidated statements of operations.

The carrying value of the convertible notes of $8.4 million immediately prior to the Company's IPO subsequently converted into 559,585 shares of common stock upon completion of the IPO.

7. Redeemable Convertible Preferred Stock Warrant Liabilities

The key terms of the redeemable convertible preferred stock warrant liabilities as of December 31, 2020 are summarized in the following table:

	Number of shares as of			
Exercisable into:	September 30, 2021	December 31, 2020	Exercise Price	Expiration
Series A-2 redeemable convertible preferred stock	—	862,471	$ 0.4996	September 30, 2021
Series C-1 redeemable convertible preferred stock	—	1,124,877	0.5289	November 16, 2021
Series D redeemable convertible preferred stock	—	1,762,810	0.7091	October 31, 2021
Total	—	3,750,158		

The fair value of the warrants was determined using an option pricing model. Under this model, the estimated equity value of the Company as of the measurement date was allocated to various classes of financial instruments (such as common and redeemable convertible preferred stock and warrants to purchase redeemable convertible preferred stock) based on their rights and preferences in an assumed liquidity scenario, which was estimated to occur in two years. Other assumptions used prior to the IPO included stock volatility ranging from 46.4% to 103.0% and risk-free interest rates ranging from 0.04% to 0.24% during the three months ended March 31, 2021. In April 2021, upon completion of the IPO, the Series A-2 and C-1 redeemable convertible preferred stock warrants were cash or net exercised into an aggregate of 61,515 shares of common stock. The Series D redeemable convertible preferred stock warrants were exchanged for 107,663 shares of common stock.

8. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock consisted of the following (in thousands, except share amounts) as of December 31, 2020:

Redeemable Convertible Preferred Stock	Shares Authorized	Shares Issued and Outstanding	Carrying Value at December 31, 2020	Aggregate Liquidation Preference
Series A-1	746,426	746,426	$ 238	$ 305
Series A-2	9,869,218	8,805,587	4,147	4,399
Series B	3,968,775	3,968,775	3,980	4,421
Series C-1	43,278,699	42,153,822	20,975	22,297
Series C-2	26,537,826	26,537,826	15,390	15,000
Series C-3	24,605,790	24,605,790	14,973	15,000
Series D	95,191,755	95,191,755	67,336	67,500
Total	204,198,489	202,009,981	$ 127,039	$ 128,922

Classification

The Company classified its redeemable convertible preferred stock as mezzanine equity on the condensed consolidated balance sheets as the shares were contingently redeemable with passage of time or upon deemed liquidation events, such as a change in control. As only the passage of time was required for Series B, C-1, C-2, C-3, and D preferred stock to become redeemable, the Company accreted the carrying value of the preferred stock shares to their redemption value, using the effective interest method, over the period from issuance to the earliest payment dates. With respect to Series A-1 and A-2, no accretion was recorded during the nine months ended September 30, 2021 and 2020, as a deemed liquidation event was not probable. Amounts recorded for the accretion of redeemable convertible preferred stock during the nine months ended September 30, 2021 and 2020 were $129,000 and $386,000, respectively. The accretion is recorded as a deemed dividend and a charge to additional paid-in capital.

In April 2021, immediately prior to the completion of the IPO (see Note 1), all outstanding shares of redeemable convertible preferred stock were automatically converted into 12,605,800 shares of common stock. Upon conversion into common stock, the carrying value of the redeemable convertible preferred stock of $127.2 million was reclassified to equity.

9. Common Stock

Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No cash dividends have been declared by the board of directors from inception.

The Company has reserved the following shares of common stock for issuance, on an as-converted basis, as follows:

	September 30, 2021	December 31, 2020
Stock incentive plans	5,103,423	2,786,345
Exercise of common stock warrants	94,688	—
Redeemable convertible preferred stock	—	12,605,800
Redeemable convertible preferred stock warrants	—	229,034
Total	5,198,111	15,621,179

10. Stock Incentive Plan

2021 Equity Incentive Plan

The Company adopted its 2021 Stock Incentive Plan, or the 2021 Plan, and the Employee Stock Purchase Plan, or the ESPP, which became effective on the date immediately prior to the date of effectiveness of the IPO. The 2021 Plan serves as the successor to its 2018 Equity Incentive Plan (the "2018 Plan"). The 2021 Plan authorizes the award of stock options, RSUs, restricted stock awards, stock bonus awards, stock appreciation rights, performance awards, and cash awards. The Company initially reserved 2,205,000 shares of its common stock for the 2021 Plan, plus any reserved shares not issued or subject to outstanding grants under the 2018 Plan on the effective date of the 2021 Plan, for issuance pursuant to awards granted under its 2021 Plan. The total number of shares reserved for issuance under the 2021 Plan upon its effective date is 2,272,613 shares

The number of Shares available for issuance under the 2021 Plan will increase automatically on January 1 of each of 2022 through 2031 by the lesser of (a) 5% of the total number of outstanding shares of all classes of its common stock on each December 31 and (b) a number as may be determined by its board of directors. The Company has reserved 276,000 shares of its common stock for the 2021 Employee Stock Purchase Plan. At September 30, 2021, options to purchase 752,631 shares under the 2021 plan remained outstanding.

2008 Plan

In September 2008, the Company's board of directors adopted the 2008 Stock Incentive Plan, or the 2008 Plan, which provides for the granting of incentive stock options, nonqualified stock options, and restricted stock awards to its employees, directors and consultants. Options granted or shares issued under the 2008 Plan that were outstanding on the date the 2018 Equity Incentive Plan, or the 2018 Plan, became effective will remain subject to the terms of the 2008 Plan. The 2008 Plan terminated in 2018 as it reached its ten-year term. At September 30, 2021 and December 31, 2020, options to purchase 542,713 and 634,788 shares, respectively, under the 2008 plan remained outstanding.

2018 Plan

In November 2018, the Company's board of directors adopted the 2018 Equity Incentive Plan. The 2018 Plan provides for the granting of incentive stock options, nonqualified stock options, restricted stock units, and other forms of stock awards to its employees, directors and consultants.

Under the 2018 Plan, the Company initially reserved 753,645 shares of common stock for issuance. In addition, any authorized shares not issued or subject to outstanding grants under the 2008 Plan and any shares subject to outstanding stock options that are cancelled without being exercised or expire under the 2008 Plan were added to the shares authorized and reserved for issuance under the 2018 Plan. In connection with the Board of Directors approval of the 2021 Plan, all remaining shares available for future award under the 2018 Plan were transferred to the 2021 Plan. At September 30, 2021 and December 31, 2020, options to purchase 1,940,910 and 1,807,101 shares, respectively, under 2018 Plan remained outstanding.

Stock Option Activity

All stock option grants are awarded at fair value on the date of grant. The fair value of stock options is estimated using the Black-Scholes option pricing model and stock-based compensation is recognized on a straight-line basis over the requisite service period. Stock options granted generally become exercisable over a four-year period from the grant date. Stock options generally expire 10 years after the grant date.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common shares for those stock options that had exercise prices lower than the fair value of the Company's common shares at September 30, 2021.

A summary of the Company's stock option activity under its stock option plans was as follows (in thousands, except share and per share data and years):

		Options Outstanding			
	Shares Available for Grant	Number of Options	Weighted -Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance — December 31, 2020	344,456	2,441,889	$ 5.17	8.02	$ 14,844
Authorized	2,205,000	—			
Granted	(1,039,474)	1,039,474	$ 12.48		
Exercised	—	(163,922)	$ 3.26		
Cancelled	81,187	(81,187)	$ 6.46		
Balance — September 30, 2021	1,591,169	3,236,254	$ 7.58	8.10	$ 20,387
Exercisable — September 30, 2021	—	1,324,112	$ 4.42	6.79	$ 12,369

As of September 30, 2021, there was $11.2 million of total unrecognized compensation cost related to unvested options that are expected to vest. The cost is expected to be recognized over a weighted-average period of 3.2 years.

In May 2020, the Company's board of directors increased the pool of stock options available for future grant by 596,414 shares and appointed an existing member of the board of directors as the Company's Chief Executive Officer. In connection with this change, the Company granted 715,358 stock options to its Chief Executive Officer at an exercise price of $7.86 per share that will vest ratably over 48 months. Vesting of the Chief Executive Officer's options accelerate upon a termination without cause. In the second quarter 2020, the Company recognized $2.1 million of expense related to a modification upon the acceleration of the former Chief Executive Officer's outstanding options upon his departure from the Company.

Stock-Based Compensation Expense

Stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 201	$ 121	$ 439	$ 365
General and administrative	777	311	1,588	2,850
Total stock-based compensation expense	$ 978	$ 432	$ 2,027	$ 3,215

In determining the fair value of the stock options granted, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective.

Fair Value of Common Stock—Prior to the IPO, given the absence of a public trading market, the Company's board of directors with input from management considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to: (1) third-party valuations of the Company's common stock; (2) the Company's stage of development; (3) the status of research and development efforts; (4) the rights, preferences and privileges of the Company's preferred stock relative to those of the Company's common stock; (5) the Company's operating results and financial condition, including the Company's levels of available capital resources; and (6) equity market conditions affecting comparable public companies; (7) general U.S. market conditions; and (8) the lack of marketability of the Company's common stock.

Expected Term—The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding. The Company used the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term.

Expected Volatility—Since the Company recently completed its IPO and does not have substantial trading history for its common stock, the expected volatility was estimated based on the average historical volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle and area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Dividend—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of stock option awards granted to employees was estimated at the date of grant using a Black-Scholes-Merton option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Expected term (in years)	6.1	6.1	6.1	6.1
Expected volatility	74.4% - 75.2%	60.9%	59.2% - 85.5%	57.6% - 60.9%
Risk-free interest rate	0.81% - 0.94%	0.25%	0.42% - 0.94%	0.27% - 1.55%
Expected dividends	—	—	—	—

11. Income Taxes

To calculate the interim tax provision, at the end of each interim period the Company estimates the annual effective tax rate and applies that to its quarterly earnings from continuing operations. The effect of changes in the enacted tax laws or rates is recognized in the interim period in which the change occurs. The computation of the annual estimated effective tax rate at each interim period requires certain estimates and judgments including, but not limited to, the expected operating income for the year, projections of the proportion of income earned and taxed in foreign jurisdictions, permanent differences between book and tax amounts, and the likelihood of recovering deferred tax assets generated in the current year. The accounting estimates used to compute the provision for income taxes may change as new events occur, additional information is obtained, or the tax environment changes.

The Company's effective tax rate for the nine months ended September 30, 2021 and 2020 differs from the U.S. statutory rate due to the U.S. valuation allowance and foreign income taxed at local statutory rates.

During the three and nine months ended September 30, 2021, the Company reported U.S. pre-tax losses, consistent with prior years to date. The Company has not yet been able to establish a sustained level of profitability in the U.S. or other sufficient significant positive evidence to conclude that its U.S. deferred tax assets are more likely than not to be realized. Therefore, the Company continues to maintain a valuation allowance against its U.S. deferred tax assets.

12. Defined Contribution Plan

The Company has a defined contribution retirement savings plan under Section 401(k) of the IRC. This plan allows eligible employees to defer a portion of their annual compensation on a pre-tax or after-tax basis. The Company makes discretionary matching contributions of up to 4% of a participating employee's salary. For the three and nine months ended September 30, 2021, the amount expensed under the plan was $85,000 and $266,000 respectively. For the three and nine months ended September 30, 2020, the amount expensed under the plan was $70,000 and $228,000, respectively.

13. Net Loss Per Share Attributable to Common Stockholders

The following outstanding shares of potentially dilutive securities were excluded from the computation of the diluted net loss per share attributable to common stockholders for the periods presented because their effect would have been anti-dilutive:

	Nine Months Ended September 30,	
	2021	2020
Redeemable convertible preferred stock on an as-converted basis	—	12,592,799
Redeemable convertible preferred stock warrants on an as-converted basis	—	134,399
Warrants to purchase common stock	94,688	—
Stock options to purchase common stock	3,236,254	2,513,002
Total	3,330,942	15,240,200

14. Subsequent Events

[TBD]

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our final prospectus, dated April 23, 2021, filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Prospectus.

In addition to historical financial information, this discussion and other parts of this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, based upon current expectations that involve risks and uncertainties. As discussed in the section titled "Special Note Regarding Forward Looking Statements," our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below.

Overview

We are a commercial-stage pharmaceutical company developing transformative therapies for people suffering from diseases with high unmet medical needs, with an initial focus on diseases of the central nervous system, or CNS. Our company was founded on the premise that the upper nasal cavity can be an optimal treatment entry point for CNS and other diseases where rapid vascular absorption can result in superior clinical outcomes. Our strategy is to pair our proprietary Precision Olfactory Delivery, or POD, upper nasal delivery technology with well-established therapeutics or other therapeutics where rapid vascular absorption is preferred to drive therapeutic benefit, improve patient outcomes, reduce drug development risk and expand the commercial opportunity within our target diseases. On September 2, 2021 Trudhesa was approved by the U.S. Food and Drug Administration, or FDA, for the acute treatment of migraine headaches with or without aura in adult patients available by prescription in pharmacies. Since 2016, we have identified and advanced multiple product candidates, including TrudhesaTM(INP104) for the acute treatment of migraine and INP105 for the acute treatment of agitation and aggression in patients with Autism Spectrum Disorder, or ASD. Our pipeline of proprietary product candidates also includes INP107 for the treatment of OFF episodes in Parkinson's Disease.

We have retained all development and commercial rights to Trudhesa and each of our product candidates. Given the concentrated prescriber base of our target market for Trudhesa and our other product candidates, we believe we will be able to independently commercialize Trudhesa and each of our existing product candidates, if approved. In the third quarter of 2021 we hired a targeted sales team of approximately 60 representatives for Trudhesa, and intend to build similar targeted sales teams for our other existing product candidates. We would then build and leverage a central organization comprised of market access, medical affairs, patient support, marketing and operations to support these distinct field teams.

We have built out an internal research and development team and also used and plan to continue to use third-party contract research organizations, or CROs, to carry out our preclinical and clinical development. We rely on third-party contract manufacturing organizations, or CMOs, to manufacture and supply our clinical materials to be used during the development of our product candidates. These CMOs are currently manufacturing commercial stage POD devices for Trudhesa, which we also used for our Phase 1 clinical trial, our registration lots and our STOP301 trial. CMOs are currently manufacturing clinical stage POD devices for INP105 and INP107, which we expect to transition to a commercial stage POD device for pivotal studies and commercialization. The development work on the commercial stage POD device for INP105 is ongoing while the commercial formulation and drug production are scaled to commercial level.

Though September 30, 2021, we have funded our operations primarily through proceeds from the sale of equity securities, including proceeds from the sale and issuance of common stock, redeemable convertible preferred stock, warrants, debt and convertible notes. We have incurred significant operating losses to date. Our net losses were $51.9 million and $32.2 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $190.1 million and a cash balance of $111.3 million.

Recent Developments

IPO and Follow-on Public Offering

In April 2021, we completed an initial public offering, or IPO, of our common stock. As part of the IPO, we issued and sold 5,333,334 shares of our common stock at a public offering price of $15.00 per share and less underwriting discounts and commissions. We received net proceeds of approximately $72.0 million from the IPO, after deducting underwriting discounts and commissions of $5.6 million and offering costs of $2.4 million.

In September 2021, we completed a follow-on public offering of our common stock, pursuant to which the we issued and sold 3,450,000 shares of our common stock (which included 450,000 shares that were offered and sold pursuant to the full exercise of the underwriters' option to purchase additional shares) at a public offering price of $15.00 per share. Including the option exercise, we received net proceeds of approximately $48.3 million after deducting underwriting discounts and commissions of $2.8 million and offering costs of $0.6 million.

COVID-19

We are continuing to proactively monitor and assess the COVID-19 global pandemic. We have been monitoring the potential impact on our business that may result from this rapidly evolving crisis and to avoid any unnecessary potential delays to our programs. The safety and well-being of employees, patients and partners is our highest priority. To date, we have continued to operate without material impact on our business.

In response to the COVID-19 pandemic, we have implemented various strategies to minimize any disruptions to commercialization of Trudhesa and our planned clinical trials. We do not expect any disruption in our supply chain of drugs necessary to initially launch Trudhesa and to conduct our clinical trials. However, we are continuing to evaluate our clinical supply chain in light of the COVID-19 pandemic. Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. We are supporting our employees by utilizing remote work, leveraging virtual meeting technology and encouraging employees to follow local guidance.

Financial Operations Overview

Product Revenues, Net

We began to recognize revenue from product sales, net of discounts and other adjustments, in September of 2021 in conjunction with the launch of Trudhesa. We recently launched Trudhesa and will continue to evaluate trends related to revenue momentum for Trudhesda, including any discernible impacts of the COVID-19 pandemic.

Cost of Goods Sold

Cost of goods sold includes direct and indirect costs related to the manufacturing and distribution of Trudhesa, including third-party manufacturing costs, packaging services, and freight-in.

Operating Expenses

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of salaries, benefits and other staff-related costs, including associated stock-based compensation, laboratory supplies, nonclinical and clinical studies and trials, manufacturing, costs for product candidates and POD devices to support our studies and trials, to design new versions of PODs, vendor validation and quality control preparation and fees paid to other entities that conduct certain research and development activities on our behalf. We consider regulatory approval of product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. We expense manufacturing costs as incurred to research and development expense for product candidates prior to regulatory approval. If, and when, regulatory approval of a product is obtained, we begin to capitalize manufacturing costs related to the approved product into inventory.

We accrue for costs incurred as the services are being provided by monitoring the status of the trial or project and the invoices received from our external service providers. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related

goods are delivered and the services are performed. In addition, we account for fully refundable research and development tax credits, based on 43.5% of qualified research and development expenditures of our Australian subsidiary, as an offset to research and development expenses.

We track our direct costs by product candidate, but we do not allocate overhead costs or certain external costs because they support multiple product candidates. In particular, with respect to internal costs, several of our departments support multiple product candidate research and development programs, and we do not allocate those costs by product candidate.

We expect to continue to incur significant research and development expenses over the next several years as our clinical programs progress and we seek to complete existing clinical studies and trials and initiate additional nonclinical and clinical studies and trials and pursue regulatory approval of our product candidates.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. Our research and development expenses may vary significantly based on factors such as:

- the phases of development of our product candidates;
- the progress and results of our research and development activities;
- the number of trials required for regulatory approval of our product candidates;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects and initiate clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing of our product candidates;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the hiring and retention of research and development personnel;
- the impact of the COVID-19 pandemic or other future pandemics on timelines and clinical operations, which may lead to increased costs, delays or both; and
- the extent to which we establish collaboration, licensing or similar arrangements and
- the performance of any related third parties.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

Selling, General and Administrative

Our selling, general and administrative expenses consist primarily of employee-related expenses, including salaries, benefits, travel and stock-based compensation for our personnel in executive, finance and accounting, human resources, and other administrative functions, as well as fees paid for accounting, legal and tax services, consulting fees and facilities costs not otherwise included in research and development expenses. With the approval of Trudhesa in September of 2021, we continue to expect our selling and marketing costs to increase relating to the commercialization of Trudhesa and further growth of our commercial infrastructure thereafter. We will incur additional expenses associated with operating as a public company, including increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services.

Other (Expense) Income, Net

Other (expense) income, net, consists of interest earned on our cash, interest expense on our borrowings, and changes in the fair value of our stock warrant liabilities, redeemable convertible preferred stock warrant liabilities and convertible notes, and loss on extinguishment of debt.

Consolidated Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following tables summarize our results of operations for the periods presented.

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Product revenue, net	$ 91	$ —	$ 91
Cost of good sold	250	—	250
Gross profit	(159)	—	(159)
Operating expenses:			
Research and development	5,929	6,133	(204)
Selling, general and administrative	16,338	2,866	13,472
Total operating expenses	22,267	8,999	13,268
Loss from operations	(22,426)	(8,999)	(13,427)
Other (expense) income, net	(2,595)	(93)	(2,502)
Loss before income taxes	(25,021)	(9,092)	(15,929)
Provision for income taxes	—	1	(1)
Net loss and comprehensive loss	$ (25,021)	$ (9,093)	$ (15,928)

Product revenue, net

We recorded net product revenue in the third quarter of 2021 following the approval of Trudhesa by the FDA in September 2021. We commenced shipments of Trudhesa during September 2021 and fully launched with a deployed sales force in October 2021. During the three months ended September 30, 2021, we recognized $0.1 million of net product revenue related to sales of Trudhesa. Sales allowances and accruals mostly consisted of co-pay card discounts and distribution fees.

Cost of goods sold

Cost of goods sold of $0.3 million for the three months ended September 30, 2021 is related to conversion and packing costs incurred after FDA approval related to the cost of Trudhesa products sold, in addition to certain overhead costs. Prior to receiving FDA approval for Trudhesa in September 2021, we recorded all costs incurred in the manufacture of Trudhesa to be sold upon commercialization as research and development expense. As a result, a portion of the manufacturing costs related to the Trudhesa build-up incurred before FDA approval were already expensed in a prior period and are therefore excluded from the cost of goods sold for the three months ended September 30, 2021. We expect to use product expensed to research and development within the next year, and accordingly we expect our cost of product sales of Trudhesa to increase as a percentage of net sales in future periods once this inventory has been sold and we produce and then sell inventory that reflects the full cost of manufacturing the product.

Research and Development

Research and development expenses were $5.9 million for the three months ended September 30, 2021, compared to $6.1 million for the three months ended September 30, 2020. The decrease of $0.2 million was primarily due to a decrease in program specific costs supporting clinical development of our product candidates, primarily for Trudhesa, as clinical trials either closed or neared completion.

The following table summarizes the period-over-period change in research and development expenses by product candidate for the periods indicated:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Program-specific costs:			
Trudhesa	$ 2,484	$ 2,853	$ (369)
INP105	939	34	905
Other programs	—	18	(18)
Total program-specific costs	3,423	2,905	518
Non program-specific costs:			
Personnel-related	$ 2,655	$ 2,577	$ 78
Internal, overhead and other expenses	(149)	651	(800)
Total non program-specific costs	2,506	3,228	(722)
Total research and development expenses	$ 5,929	$ 6,133	$ (204)

Selling, General and Administrative

Selling, general and administrative expenses were $16.3 million for the three months ended September 30, 2021, compared to $2.9 million for the three months ended September 30, 2020. The increase of $13.4 million was primarily due to the ramp up of commercial and marketing related activity to prepare for the approval of Trudhesa. Marketing and market access expenses increased by $5.2 million primarily due to fees paid to the agency of record. There was a $4.2 million increase related to sales commercial operations, which did not have any activity in the three months ended September 30, 2020. There was additionally a $1.4 million increase in finance, legal, and executive expense, specifically related to insurance fees tied to the public offering, IT related expense, and board compensation. Selling, general and administrative personnel cost increased by $2.6 million compared to the three months ended September 30, 2020.

Other (Expense) Income, Net

Other (expense) income, net was an expense of $2.6 million for the three months ended September 30, 2021, compared to $0.1 million for the three months ended September 30, 2020. The change of $2.5 million was primarily due to a (i) charge of $2.0 million for the loss on early extinguishment of debt related to the payoff of the Avenue term loan, (ii) an increase in interest expense on our borrowings of $0.3 million, and (iii) amortization of debt discount of $0.2 million.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following tables summarize our results of operations for the periods presented.

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Product revenue, net	$ 91	$ —	$ 91
Cost of good sold	250	—	250
Gross profit	(159)	—	(159)
Operating expenses:			
Research and development	16,103	19,524	(3,421)
Selling, general and administrative	30,971	12,240	18,731
Total operating expenses	47,074	31,764	15,310
Loss from operations	(47,233)	(31,764)	(15,469)
Other (expense) income, net	(4,561)	(9)	(4,552)
Loss before income taxes	(51,794)	(31,773)	(20,021)
Provision for income taxes	—	1	(1)
Net loss and comprehensive loss	$ (51,794)	$ (31,774)	$ (20,020)

Product revenue, net

We recorded net product revenue in the third quarter of 2021 following the approval of Trudhesa by the FDA in September 2021. We commenced shipments of Trudhesa during September 2021 and fully launched with a deployed sales force in October 2021. During the three months ended September 30, 2021, we recognized $0.1 million of net product revenue related to sales of Trudhesa. Sales allowances and accruals mostly consisted of co-pay card discounts and distribution fees.

Cost of goods sold

Cost of goods sold of $0.3 million for the nine months ended September 30, 2021 is related to conversion and packing costs incurred after FDA approval related to the cost of Trudhesa products sold, in addition to certain overhead costs. Prior to receiving FDA approval for Trudhesa in September 2021, we recorded all costs incurred in the manufacture of Trudhesa to be sold upon commercialization as research and development expense. As a result, a portion of the manufacturing costs related to the Trudhesa build-up incurred before FDA approval were already expensed in a prior period and are therefore excluded from the cost of goods sold for the three months ended September 30, 2021. We expect to use product expensed to research and development within the next year, and accordingly we expect our cost of product sales of Trudhesa to increase as a percentage of net sales in future periods once this inventory has been sold and we produce and then sell inventory that reflects the full cost of manufacturing the product.

Research and Development

Research and development expenses were $16.1 million for the nine months ended September 30, 2021, compared to $19.5 million for the nine months ended September 30, 2020. The decrease of $3.4 million was primarily due to a decrease in program specific costs supporting clinical development of our product candidates, primarily for Trudhesa, as clinical trials either closed or neared completion.

The following table summarizes the period-over-period change in research and development expenses by product candidate for the periods indicated:

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Program-specific costs:			
Trudhesa	$ 5,725	$ 9,796	$ (4,071)
INP105	1,625	204	1,421
Other programs	28	316	(288)
Total program-specific costs	7,378	10,316	(2,938)
Non program-specific costs:			
Personnel-related	$ 7,911	$ 7,511	$ 400
Internal, overhead and other expenses	814	1,697	(883)
Total non program-specific costs	8,725	9,208	(483)
Total research and development expenses	$ 16,103	$ 19,524	$ (3,421)

Selling, General and Administrative

Selling, general and administrative expenses were $31.0 million for the nine months ended September 30, 2021, compared to $12.2 million for the nine months ended September 30, 2020. The increase of $18.8 million was primarily due to the ramp up of commercial and marketing related activity to prepare for the approval of Trudhesa. Sales related expenses increased by $3.5 million, marketing and market access expense increased by $8.4 million, and commercialization expense increased by $3.5 million. Finance, legal, and executive expense increased by $2.5 million primarily due to the increase in IT related expense, board compensation and recruiting fees in 2021. Selling, general and administrative personnel cost increased by $1 million compared to the nine months ended September 30, 2020, driven by an increase in headcount.

Other (Expense) Income, Net

Other (expense) income, net was an expense of $4.6 million for the nine months ended September 30, 2021, compared to expense of $9,000 for the nine months ended September 30, 2020. The change of $4.6 million was primarily due to a (i) charge of $2.0 million for the loss on early extinguishment of debt related to the payoff of the Avenue term loan, (ii) an increase in interest expense on our borrowings of $0.9 million, (iii) a loss from the change in fair value of the convertible notes of $0.8 million, (iv) amortization of debt discount of $0.5 million and (v) a loss from the change in fair value of our warrant liabilities of $0.2 million.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. Through September 30, 2021, we have funded our operations primarily through the issuance of common stock, convertible promissory notes, redeemable convertible preferred stock, debt, warrants and convertible notes with aggregate proceeds of $292.8 million. As of September 30, 2021, we had available cash and cash equivalents of $111.3 million and an accumulated deficit of $190.1 million.

Based upon our current operating plan, we estimate that our cash and cash equivalents as of September 30, 2021, are together sufficient for us to fund operating, investing, and financing cash flow needs for at least one year from the issuance date of our interim financial statements. If sufficient funds on acceptable terms are not available when needed, we could be required to reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs or planned product launch plans. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact our ability to achieve its intended business objectives.

In September 2021, we completed a follow-on public offering of our common stock, pursuant to which we issued and sold 3,450,000 shares of common stock (which included 450,000 shares that were offered and sold pursuant to the full exercise of the underwriters' option to purchase additional shares) at a public offering price of $15.00 per share. Including the option exercise, we received net proceeds of approximately $48.3 million after deducting underwriting discounts and commissions of $2.8 million and offering costs of $0.6 million.

In July 2021, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford, as the collateral agent and a lender, and Silicon Valley Bank, or SVB and, together with Oxford, the Lenders, as a lender to borrow up to an aggregate principal amount of $50.0 million in a series of term loans. Upon entering into the Loan Agreement, we borrowed $20.0 million, or the Term A Loan, from Oxford and SVB, or the Lenders, with approximately $10.8 million of such amount applied to the repayment of the outstanding principal, interest and final payment fees owed pursuant to our prior loan and security agreement with Avenue Ventures dated November 5, 2020. Under the terms of the Agreement, we may, at our sole discretion, borrow up to an additional $10.0 million, or the Term B Loan, upon the achievement by us of NDA approval from the FDA of Trudhesa which we drew down on the entire $10.0 million on September 30, 2021. Under the terms of the Loan Agreement, we may, at our sole discretion, borrow from the Lenders up to an additional $20.0 million, or the Term C Loan, upon the achievement by us of net revenue for a trailing six (6) month period of at least $15.0 million, or the Term C Milestone Event. We may draw the Term C Loan during the period commencing on the date of the occurrence of the Term C Milestone Event and ending on the earliest of (i) December 31, 2022 (ii) the sixtieth (60th) day following the occurrence of the Term C Milestone Event, and (iii) the occurrence of an event of default.

In connection with entering into the Loan Agreement and borrowing the Term A Loan and Term B Loan, we issued warrants to purchase 71,522 and 23,166 shares of common stock, respectively, or the Warrants, to the Lenders at a per share exercisable price of $8.389 and $12.95, respectively.

In April 2021, we completed an IPO, of our common stock. As part of the IPO, we issued and sold 5,333,334 shares of our common stock at a public offering price of $15.00 per share. We received net proceeds of approximately $72.0 million from the IPO, after deducting underwriting discounts and commissions of $5.6 million and offering costs of $2.4 million.

In March 2021, we issued convertible promissory notes to various investors for an aggregate amount of $7.5 million. The notes bore interest at a rate of 5.0% per annum and matured on the earlier of (a) December 31, 2021 and (b) a change of control. The notes were (i) automatically convertible into shares of our common stock upon a Qualified Public Offering or a SPAC transaction at 90% of the price per share in such transactions, (ii) convertible at the holder's option or upon a change of control into shares of Series D redeemable convertible preferred stock at the Series D original issuance price, and (iii) convertible at the holder's option upon a new redeemable convertible preferred stock financing into shares of redeemable preferred stock issued in such financing at 90% of the price per share. In April 2021, upon completion of our IPO, these convertible promissory notes were converted into 559,585 shares of common stock.

In November 2020, we entered into a debt and equity financing agreement, or the Avenue Agreement, with Avenue. The Avenue Agreement provided for a 36-month term loan of up to $20.0 million, of which $10.0 million was funded at close and an additional $10.0 million was available at our request until December 31, 2021, subject to (i) completion of an underwritten public offering with gross proceeds of at least $75.0 million, or a Qualified Public Offering, (ii) receipt of FDA approval of Trudhesa and (iii) approval by Avenue's investment committee. Loans under the Avenue Agreement incur interest at an initial interest rate of 11% per year. On July 2, 2021, we repaid approximately $10.8 million of outstanding principal, interest and final payment fees owed under the Avenue Agreement and terminated the Avenue Agreement. We recorded a loss of $2.0 million on the early extinguishment of debt related to the unamortized debt discount associated with the fair value of the warrants, final payment fee, and unamortized debt issuance costs.

We also issued a warrant to Avenue to purchase, at its option, either 1,762,810 shares of our Series D redeemable convertible preferred stock or a number of shares of the preferred stock issued in our next preferred stock equity financing determined based on the sale price of such preferred stock. In April 2021, upon completion of our IPO, this warrant was automatically exchanged for 107,663 shares of common stock for no additional consideration.

Cash Flows

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Cash used in operating activities	$ (43,170)	$ (28,887)
Cash used in investing activities	(264)	(893)
Cash provided by financing activities	147,628	1,067
Net increase (decrease) in cash	$ 104,194	$ (28,713)

Cash Flows From Operating Activities

For the nine months ended September 30, 2021, cash used in operating activities was $43.2 million, which consisted of a net loss of $51.8 million partially offset by a net change of $2.1 million in operating assets and liabilities and by $6.6 million in non-cash charges. The net change in our operating assets was primarily due to an increase in prepaid expenses and other current assets of $5.9 million offset by an increase in accounts payable and accrued liabilities of $8.0 million due primarily to an increase in the level of selling, general and administrative expenses. The non-cash charges primarily consisted of stock-based compensation, depreciation and amortization, loss on early extinguishment of debt, amortization of debt discount, inventory write-downs to net realizable value, a change in the fair value of convertible notes, and a change in the fair value of our warrant liabilities.

For the nine months ended September 30, 2020, cash used in operating activities was $28.9 million, which consisted of a net loss of $31.8 million and a net change of $1.0 million in operating assets and liabilities, partially offset by $4.0 million in non-cash charges The net change in our operating assets was primarily due to a decrease in accounts payable and accrued liabilities of $1.8 million partially offset by a decrease in prepaid expenses and other current assets of $0.7 million. The non-cash charges primarily consisted of stock-based compensation, depreciation and amortization, and change in the fair value of our redeemable convertible preferred stock warrant liabilities.

Cash Flows From Investing Activities

For the nine months ended September 30, 2021 and 2020, cash used in investing activities of $0.3 and $0.9 million, respectively, was related to purchases of property and equipment.

Cash Flows From Financing Activities

For the nine months ended September 30, 2021, cash provided by financing activities was $147.6 million, consisting primarily of net proceeds received from our IPO of $72.0 million and follow-on offering of $48.3 million net of issuance costs, net proceeds of $19.1 million under the Loan Agreement, proceeds of $7.5 million from the issuance of convertible notes and to a lesser extent from exercises of stock options and exercise of redeemable convertible preferred stock warrants.

For the nine months ended September 30, 2020 there were no significant movements in cash.

Funding Requirements

We use our cash to fund operating expenses, including research and development expenditures and commercialization expenses for Trudhesa. We will incur significant commercialization expenses for product sales, marketing and outsourced manufacturing with respect to Trudhesda. We plan to continue to incur research and development expenses for the foreseeable future as we continue clinical trials and move further into product candidate development. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs primarily through a combination of equity or debt financings.

The timing and amount of our operating expenditures will depend largely on:

- the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution for Trudhesa, or any of our product candidates for which we receive marketing approval;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number and development requirements of other product candidates that we may pursue;
- the costs associated with building out our operations;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish strategic collaborations;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapies that compete with our product candidates; and
- the costs associated with being a public company.

If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to additional liens against potentially all of our assets and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our management's discussion and analysis of our financial condition and consolidated results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenue generated, and reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Except for the revenue recognition, inventory, cost of goods sold and accounts receivable policies described below (also in Note 2 Summary of Significant Accounting Policies), there have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Prospectus.

Revenue Recognition

We recognize revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services.

Product Revenue, Net

Subsequent to its regulatory approval in the U.S. in September 2021, the Company began to sell Trudhesa in the U.S. The product is distributed through an exclusive third-party logistics, or 3PL, distribution agent that does not take title to the product. The 3PL distributes Trudhesa to the customers, a specialty pharmacy and a specialty distributor (collectively referred to as "customers"), who then distribute the product to health care providers and patients. In our exclusive distribution agreement with the 3PL company, we act as principal because we retain control of the product.

Revenue from product sales is recognized when the customer obtains control of our product, which occurs upon transfer of title to the customer. We classify payments to customers or other parties in the distribution channel for services that are distinct and priced at fair value as selling, general and administrative expenses in our condensed consolidated statements of operations. Payments to customers or other parties in the distribution channel that do not meet those criteria are classified as a reduction of revenue, as discussed further below. Taxes collected from the customer relating to product sales and remitted to governmental authorities are excluded from revenue. Because our payment terms are generally forty-five days, we conclude there is not a significant financing component because the period between the transfer of a promised good or service to the customer and when the customer pays for that good or service will be one year or less. We expense incremental costs of obtaining a contract as and when incurred since the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, or the transaction price, which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, co-pay assistance, chargebacks, rebates and other allowances that are offered within contracts between us and our customer, health care providers and other indirect customers relating to the sale of Trudhesa. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following are the components of variable consideration related to product revenue:

Product Returns: Our customer has limited return rights related to the product’s damage or defect. We estimate the amount of product sales that may be returned and records the estimate as a reduction of revenue and a refund liability in the period the related product revenue is recognized. Based on the distribution model for Trudhesa and the price of Trudhesa, we believe there will be minimal returns.

Other incentives: Other incentives include co-payment assistance we provide to patients with commercial insurance that have coverage and reside in states that allow co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue. The estimate is recorded as a reduction of revenue in the same period the related revenue is recognized.

Managed care rebates: We maybe be subject to rebates with certain commercial payers in the future. We will record these rebates as an accrual on our condensed consolidated balance sheet in the same period we recognize the related revenue. We will estimate our managed care rebates based on our estimated payer mix and the applicable contractual rebate rate.

Chargebacks: We estimate obligations resulting from contractual commitments with the government and other entities to sell products to qualified healthcare providers and patients at prices lower than the list prices charged to our customer. The government and other entities charge us for the difference between what they pay for the product and the selling price to our customer. We records reserves for these chargebacks related to product sold to our customer during the reporting period, as well as our estimate of product that remains in the distribution channel at the end of the reporting period that we expect will be sold to qualified healthcare providers and patients in future periods. As of September 30, 2021, we did not enter into any contracts with government entities and other entities that are eligible for chargebacks.

Government rebates: We are subject to discount obligations under government programs, including Medicaid programs, Medicare and Tricare in the U.S. We estimate Medicaid, Medicare and Tricare rebates based upon a range of possible outcomes that are

probability-weighted for the estimated payer mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability that is included in accrued expenses on our consolidated balance sheet. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. On a quarterly basis, we update our estimates and record any adjustments in the period that we identify the adjustments.

Accounts Receivable, net

Our trade accounts receivable consists of amounts due from specialty pharmacies in the U.S. net of distribution service fees, prompt pay discounts and other adjustments. Our contracts with customers have standard payment terms that generally require payment within 45 days. We analyze accounts that are past due for collectability, and periodically evaluates the creditworthiness of its customers. As of September 30, 2021, we determined an allowance for doubtful accounts was not required based upon our review of contractual payment terms and individual customer circumstances.

Inventory

Prior to receiving approval from the FDA in September 2021 to sell Trudhesa in the U.S., we expensed all costs incurred related to the manufacture of Trudhesa as research and development expense because of the inherent risks associated with the development of a drug candidate, the uncertainty about the regulatory approval process and the lack of history for our regulatory approval of drug candidates. Subsequent to receiving FDA approval in September 2021, we began to capitalize inventory related costs that were incurred subsequent to FDA approval. we value our inventories at the lower-of-cost or net realizable value and determine the cost of our inventories, which includes costs related to products held for sale in the ordinary course of business, products in process of production for such sale and items to be currently consumed in the production of goods to be available for sale, on a first-in, first-out (FIFO) basis. Due to the nature of our supply chain process, inventory that is owned by us, is physically stored at third-party warehouses, logistics providers and contract manufacturers. We perform an assessment of the recoverability of capitalized inventory during each reporting period, and write down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified. If they occur, such impairment charges are recorded as a component of cost of goods sold in the condensed consolidated statements of operations and comprehensive loss.

Cost of Goods Sold

Cost of goods sold consists primarily of third-party manufacturing, distribution, and overhead costs associated with Trudhesa. A portion of the costs of producing Trudhesa sold to date was expensed as research and development prior to the FDA approval of Trudhesa and, therefore, it is not reflected in the cost of goods sold.

Cost of goods sold for the three months ended September 30, 2021, included a charge of $0.1 million related to the write down of inventory to net realizable value in the condensed consolidated statements of operations and comprehensive loss.

Recent Accounting Pronouncements

See Note 2—Basis of Presentation and Significant Accounting Policies to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period to enable us to get comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305 of Regulation S-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

We are not party to any material legal proceedings at this time. From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business.

Item 1A. Risk Factors.

RISK FACTORS

Our business involves significant risks, some of which are described below. Before making your decision to invest in shares of our common stock, you should carefully consider the risks and uncertainties described below, together with the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently believe are not material may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.

Risk Factor Summary

The following summarizes the most material risks that make an investment in our securities risky or speculative. If any of the following risks occur or persist, our business, financial condition and results of operations could be materially harmed and the price of our common stock could significantly decline.

- The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for INP105, INP107 or any other product candidates.
- Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, health care payors and others in the medical community necessary for commercial success.
- We are a commercial-stage pharmaceutical company with a limited operating history and have incurred net losses since our inception. We anticipate that we will continue to incur substantial operating losses for the foreseeable future and we may never achieve or sustain profitability.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates on unfavorable terms to us.
- Clinical failure may occur at any stage of clinical development, and we may never succeed in developing marketable product candidates or generating product revenue.
- Delays in the commencement, enrollment or completion of clinical trials of our product candidates, or in the acceptance of foreign clinical trial data, could result in increased costs to us as well as a delay or failure in obtaining regulatory approval, or prevent us from commercializing our product candidates on a timely basis, or at all.
- The outbreak of COVID-19, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including through disruption to our planned clinical trials, supply chains, business operations and commercialization efforts for Trudhesa and our other product candidates.
- We rely entirely on third parties for the manufacturing of product candidates that we develop for nonclinical studies and clinical trials and expect to continue to do so for commercialization. If we encounter difficulties in negotiating manufacturing and supply agreements with third-party manufacturers and suppliers of our POD device and the active ingredients in Trudhesa, INP105, and INP107, our ability to commercialize our product candidates, if approved, would be impaired.
- If we are not able to obtain and enforce patent protection for our technologies or product candidates, development and commercialization of our technology and product candidates may be adversely affected.

- We may encounter difficulties in managing our growth and expanding our operations successfully.
- If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.

Risks Related to Our Financial Position and Need for Additional Capital

We are a commercial-stage biopharmaceutical company and have incurred net losses since our inception. We anticipate that we will continue to incur substantial operating losses for the foreseeable future and we may never achieve or sustain profitability.

We are a commercial-stage biopharmaceutical company formed in 2008. Since inception, we have devoted substantially all of our financial resources to research and development, including our clinical and nonclinical development activities. To date, we have financed our operations primarily through the sale and issuance of redeemable convertible preferred stock, convertible notes and warrants, and the completion of our initial public offering, or IPO.

We have incurred significant net losses since our inception. Our net losses were $51.9 million and $45.8 million for the nine months ended September 30, 2021 and the year ended December 31, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $190.1 million. We cannot predict when or whether we will become profitable. To date, we have not generated any product revenues, and we may never be able to develop or commercialize a marketable product. Our losses have resulted principally from costs incurred in our product candidate discovery and development activities. We expect to incur net losses for the foreseeable future.

Our financial position will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or additional grants. If we are required by the FDA, or any equivalent foreign regulatory authority, to perform clinical trials or studies in addition to those we currently expect to conduct, including if foreign clinical trial data are not accepted by the FDA, or if there are any delays in completing the clinical trials of our product candidates, our expenses could increase substantially. Although we have recently received approval for Trudhesa, the resulting revenue from its commercialization may not enable us to achieve profitability. Even if we obtain regulatory approval to market additional product candidates, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidates in those markets.

We expect our expenses and net losses to increase significantly as we prepare to commercialize Trudhesa, continue our development of, and seek regulatory approvals for, our other product candidates, and begin to commercialize other approved products as well as hire additional personnel, protect our intellectual property and incur additional costs associated with operating as a public company. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical studies and trials, associated manufacturing needs, commercialization activities if our other product candidates are approved and our expenditures on other research and development activities.

To become and remain profitable, we must successfully develop product candidates, obtain regulatory approval for them, and manufacture, market and sell those product candidates for which we may obtain regulatory approval. We may not succeed in these activities and we may never generate revenue from product sales that are significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business for any reason, including as a result of the COVID-19 pandemic. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our business could cause you to lose all or part of your investment.

We will require substantial additional financing to achieve our goals and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of September 30, 2021, we had $111.3 million of cash and cash equivalents. We believe that we will continue to expend substantial resources for the foreseeable future as we prepare for the commercialization of Trudhesa, develop additional product candidates, continue clinical trials for our existing product candidates and pursue commercialization of our product candidates, if approved. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Our costs will increase if we suffer any delays in our planned clinical trials for our current product candidates. We expect to incur additional costs associated with operating as a public company, hiring additional personnel and potentially expanding our facilities.

We believe our existing cash and cash equivalents of approximately $111.3 million as of September 30, 2021, will fund our projected operating requirements for at least 15 months. Our forecast of the period of time through which our financial reserves will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. For further details regarding the terms of the Loan Agreement, see "Management's Discussion and Analysis—Liquidity and Capital Resources—Sources of Liquidity." We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the cost of commercialization activities for Trudhesa, or any other approved product, including marketing, sales and distribution costs;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful;;
- the scope, progress, results and costs of developing and advancing our product candidates through clinical trials and researching and discovering new product candidates;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- our ability to generate revenue from approved product candidates, if any; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation.

We will need to raise additional funds to address our goals. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate nonclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize Trudhesa and our other product candidates if approved.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates on unfavorable terms to our business.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such equity or convertible debt securities may include liquidation or other preferences that are senior to or otherwise adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. For example, our Loan Agreement is secured by a lien on substantially all of our assets, excluding our intellectual property and includes a negative pledge regarding our intellectual property. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variation in the level of expense related to the commercialization of Trudhesa or any other product candidates that receives regulatory approval, and quarterly fluctuations in product sales or Trudhesa or any other product candidates that receives regulatory approval;

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results of nonclinical and clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receive regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results should not be relied upon as an indication of our future performance.

Risks Related to Regulatory Review and Approval of Our Product Candidates

The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for INP105, INP107 or any other product candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to INP105 and INP 107, our furthest advanced product candidates under clinical development, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing approval of drugs in the United States requires the submission of an NDA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the NDA for that product. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, CMC, and current good manufacturing practices, or cGMP, at the manufacturing facilities. Further, our product candidates must be approved by comparable regulatory authorities in other jurisdictions where we intend to market our product candidates prior to commercialization.

FDA approval of an NDA is not guaranteed, and review and approval is an expensive and uncertain process that may take several years. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, there can be no assurance that any of our other product candidates will receive regulatory approval in the United States, or other jurisdictions. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for NDA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. We intend to seek FDA approval for our product candidates through the Section 505(b)(2) regulatory pathway. If the FDA does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for one or more of our product candidates, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the pharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a product candidate for many reasons, including because the FDA:

- may not deem our product candidate to be safe and effective;
- determines that the product candidate does not have an acceptable benefit-risk profile;
- determines in the case of an NDA seeking accelerated approval that the NDA does not provide evidence that the product candidate represents a meaningful advantage over available therapies;
- determines that the objective response rate, or ORR, and duration of response are not clinically meaningful;
- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status;
- may conclude there are CMC issues that preclude approval of the NDA;
- may conclude that the drug substance or drug product manufacturing process is not in a state of control or does not meet cGMPs or all the regulatory requirements;
- may not be able to timely conduct the necessary pre-approval inspection or devote sufficient resources to NDA review on a timely basis due to the COVID-19 pandemic;
- may change approval policies or adopt new regulations; or
- may not file a submission due to, among other reasons, the content or formatting of the submission.

We have not obtained FDA approval for any of our product candidates. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for our clinical product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of INP105 or INP107, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

Clinical failure may occur at any stage of clinical development, and we may never succeed in developing marketable product candidates or generating product revenue.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing.

Although the active ingredients in our other product candidates, INP105 and INP107, are approved or commonly used as treatments for migraine, agitation associated with ASD, and Parkinson's, respectively, they have not previously been approved or demonstrated to be safe for chronic use over an extended period of time using an upper nasal cavity drug delivery. Any future NDA submissions may propose to bridge Listed Drugs, or LDs, for which we have conducted comparative bioavailability study. The approval of Trudhesa or our prior clinical results for our product candidates are not necessarily indicative of our ability to bridge to LD for future product candidates, as there can be significant variability in results between different clinical trials due to numerous factors, including changes in trial procedures, differences in the size and type of patient populations, including across geographies, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants. If we are not able to establish a bridge between a product candidate and each LD upon which they rely to demonstrate that such reliance is justified, we may be required to show safety and efficacy through one or more clinical trials. In addition, the long-term safety studies we are conducting or plan to conduct may reveal safety concerns, including with regard to nasal mucosa or olfactory function. If either or both of these outcomes occur, we may be prevented or delayed in obtaining marketing approval.

We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on our distribution, such as in the form of a Risk Evaluation and Mitigation Strategy, or REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would materially and adversely affect our business, results of operations and financial condition.

Delays in the commencement, enrollment or completion of clinical trials of our product candidates could result in increased costs to us as well as a delay or failure in obtaining regulatory approval, or prevent us from commercializing our product candidates on a timely basis, or at all.

We plan to initiate a Phase 2 trial of a double-blind placebo-controlled single dose of INP105 study in adolescents with ASD by the end of 2021. Any of our future clinical trials may not be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include:

- delays by us in reaching a consensus with regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- delays in recruiting suitable patients to participate in clinical trials;
- the effects of COVID-19 on our ability to recruit and retain patients, including as a result of potential heightened exposure to COVID-19, prioritization of hospital resources toward the outbreak and unwillingness by patients to enroll or comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services;
- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns or after an inspection of clinical operations or trial sites;
- failure by CROs, other third parties or us to adhere to clinical trial requirements;
- failure to perform clinical trials in accordance with the FDA's good clinical practices, or GCP, or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays caused by patients not completing participation in a trial or not returning for post-treatment follow-up, which we have experienced and believe may be caused by patients experiencing reduced symptoms or incidences of disease;
- clinical trial sites or patients dropping out of a trial;
- delays or interruptions to supply or failure to ensure compliance with cGMP or quality standards of our product candidates or the other product candidates in a combination product trial or other materials necessary to conduct clinical trials of our product candidates;
- occurrence of adverse events in clinical trials that are associated with the product candidates that are viewed to outweigh their potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Delays, including delays caused by any of the above factors, can be costly and could negatively affect our ability to complete a clinical trial. If we are not able to successfully complete clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

If we are not able to use the 505(b)(2) regulatory approval pathway for regulatory approval of any of our other product candidates or if the FDA requires additional clinical or nonclinical data to support an NDA under Section 505(b)(2) than we have previously anticipated, it will likely take significantly longer, cost significantly more and be significantly more complicated to gain FDA approval for our product candidates, and in any case may not be successful.

We intend to seek FDA approval for product candidates through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or the FDCA. In general, Section 505(b)(2) allows a 505(b)(2) applicant to rely on the FDA's finding of safety or effectiveness for an LD only to the extent that the proposed product in the 505(b)(2) application shares common

characteristics with the LD. The 505(b)(2) application must include sufficient data to support differences between the LD and the proposed drug in the 505(b)(2) application. If the FDA does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for one or more of our product candidates, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. For example, the FDA may not agree that we have provided a scientific bridge, through, for example, comparative bioavailability data, to demonstrate that reliance on the prior findings of safety or efficacy for an LD is justified. If we are unable to pursue a Section 505(b)(2) pathway, the time and financial resources required to obtain FDA approval for our product candidates would likely increase substantially. Moreover, the inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects.

Even though Trudhesa was approved through the Section 505(b)(2) regulatory pathway, we cannot assure you that nonclinical studies or clinical trials that we have conducted or that we currently anticipate conducting will be sufficient for approval or that we will receive the requisite or timely approvals for commercialization of any other product candidate. Although the Section 505(b)(2) pathway allows us to rely in part on the FDA's prior findings of safety or efficacy for approved LDs or on published literature, the FDA may determine that prior findings by the FDA or the published literature that we believe supports the safety or efficacy of one or more of our product candidates is insufficient or not applicable to our application or that additional studies will need to be conducted. To the extent that we are relying on the Section 505(b)(2) regulatory pathway based on the approval of an LD for a similar indication, the FDA may require that we include in the labeling of such our other product candidates, if approved, some or all of the safety information that is included in the labeling of the approved LD. Our approved labeling for Trudhesa includes the safety information included in the labeling of the approved LD used for our Trudhesa NDA, as well as the efficacy information for the LD, including a Black Box Warning. Moreover, even if our product candidates are approved through the Section 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

The outbreak of COVID-19, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including through disruption to our planned clinical trials, supply chains, business operations and commercialization efforts, or through delay in the FDA's approval of our product candidates.

The COVID-19 global pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, potential waves or cycles of the pandemic or new virus variants, and the actions to contain the virus or treat its impact. For example, ineffective or uncoordinated vaccine deployment or other responses to COVID-19, the emergence of more virulent or infectious variants of the virus, or limitations on vaccine availability could risk increasing the duration and severity of the pandemic, which could have various negative impacts on our business, the extent of which we cannot fully predict.

Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis for our planned clinical trials may be delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. Additionally, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our planned clinical trials. If the global effort to control the spread of COVID-19 and treat COVID-19 patients continues on the current trajectory for an extended period of time, we risk a delay in activating sites and enrolling subjects as previously projected. Any such delays to our planned clinical trials for our current product candidates could impact the use and sufficiency of our existing cash reserves, and we may be required to raise additional capital earlier than we had previously planned. We may be unable to raise additional capital if and when needed, which may result in further delays or suspension of our development plans.

Further, as a result of the COVID-19 public health emergency, we may be required in the future to develop and implement additional clinical trial policies and procedures based on new guidance and regulatory requirements promulgated by the FDA or other regulatory authorities. For example, the FDA issued guidance in March 2020, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describe a number of considerations for sponsors of clinical trials impacted by the pandemic. In June 2020, the FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs. Additional COVID-19 related guidance released by the FDA includes guidance addressing resuming normal drug and biologics manufacturing operations; manufacturing, supply chain, and inspections; and statistical considerations for clinical trials during the COVID-19 public health emergency.

Infections and deaths related to COVID-19 also continue to disrupt certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of our product candidates.

The COVID-19 pandemic could have an adverse impact on our commercial launch plans for Trudhesa due to the continuation of government-imposed quarantines, stay at home orders, travel restrictions, mandated business closures and other public health safety measures which may result in limiting our ability to hire a sales force prior to launch, conduct necessary trainings of such sales force and attending and presenting at various conferences or other programs. Even though Trudhesa has been approved by the FDA, continuation of these government-imposed orders may also result in patients not visiting their healthcare providers or their pharmacies to get their prescriptions filled, in-person interactions by sales and medical representatives in healthcare settings may be suspended, and any remote interactions may be less effective than in-person interactions. In addition, due to the prioritization of healthcare resources toward pandemic efforts, even remote interactions may not be possible. These factors could have an adverse impact on our business and our ability to effectively launch Trudhesa.

We currently utilize third parties to, among other things, manufacture raw materials and our product candidates, components, parts, and consumables, and to perform quality control and testing. If either we or any third-party in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture product candidates for our clinical trials.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material adverse effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets and the trading prices of pharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the global effort to control COVID-19 infections could materially and adversely affect our business.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our planned clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our business, financial condition and results of operations.

Our marketed product and all of our development product candidates utilize similar drug delivery devices. If a drug delivery device in one of our clinical trials demonstrates unanticipated biocompatibility, usability, performance or safety issues in a clinical or nonclinical study for one product candidate, our entire pipeline may be adversely affected.

Our marketed product and all of our development product candidates utilize similar POD devices, which are designed to deliver the drug into the upper nasal cavity using a gas propellant. While our product candidates have been generally well tolerated in nonclinical studies and early clinical trials, patients may in the future experience different or more severe adverse events due in part to our POD device. Any failure of our POD device to demonstrate adequate biocompatibility, usability, performance or safety could adversely affect the development, approval, or commercialization of Trudhesa or our other product candidates utilizing the same or similar POD device, including a suspension or delay of all ongoing development in our other product candidates, or our marketed product candidates, if any.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of nonclinical studies and clinical trials and the submission of regulatory filings. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to reach subsequent milestones, receive marketing approval or commercialize our product candidates, including:

- the FDA and other governmental health authorities, IRBs, or ethics committees may not authorize or may delay authorizing us or our investigators to commence or continue a clinical trial or conduct a clinical trial at all or at a prospective trial site, such as by requiring us to conduct additional nonclinical studies and to programs for our product candidates submit additional data or imposing other requirements before permitting us to initiate or continue a clinical trial;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct nonclinical studies in addition to those we currently have planned or additional clinical trials or we may decide to abandon drug development programs for our product candidates;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our contractors, such as our CROs, clinical trial sites or investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that, we or our investigators, suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to health risks;
- the cost of planned clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our third-party suppliers, such as our contract manufacturers of the POD device and our active ingredients, may not provide us with the information we need for our marketing submissions or may not manufacture product for us that is in compliance with regulatory requirements; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from nonclinical or clinical testing of studies conducted by competitors that raise safety or efficacy concerns broadly about our POD technology, upper nasal cavity delivery or about our product candidates specifically.

Clinical development, regulatory review and approval by the FDA and comparable foreign authorities are lengthy, time consuming, costly, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

Our marketed product and development product candidates are subject to extensive governmental regulation relating to, among other things, development, clinical trials, manufacturing and commercialization. In order to obtain regulatory approval for the commercial sale of any of our product candidates, we must demonstrate through extensive nonclinical studies and clinical trials that the candidate is safe and effective for use in each target indication.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the acceptance of clinical data developed in foreign geographies. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve a product candidate. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. In addition, we may gain regulatory approval in some but not all of the territories available or some but not all of the target indications, resulting in limited commercial opportunity for the approved product.

Applications for our product candidates could be delayed or could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies clinical trials or may refuse to accept data from nonclinical studies or clinical trials conducted in other geographies or jurisdictions;

- data collected from clinical trials may not be sufficient to support the submission of an NDA, or other submission, or to obtain regulatory approval in the United States or elsewhere;
- the FDA may determine that we cannot rely on the Section 505(b)(2) approval pathway for any of our product candidates, in which case we may be required to conduct additional clinical trials, provide additional data and information and meet additional standards for product approval, resulting in increased time and financial resources required to obtain FDA approval for our product candidates;
- the FDA may determine that we have identified the wrong LD or LDs or that approval of a Section 505(b)(2) application for any of our product candidates is blocked by patent or non-patent exclusivity of the LD or LDs;
- the FDA may require us to conduct additional clinical trials depending on the safety or exploratory efficacy data from our existing and planned future clinical trials;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for our proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications of third-party manufacturers with which we contract for clinical and commercial supplies;
- we or any third-party manufacturers may be unable to demonstrate compliance with cGMP to the satisfaction of the FDA or comparable foreign regulatory authorities, which could result in delays in regulatory approval or require us to withdraw or recall product candidates and interrupt commercial supply of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

Inadequate funding for the FDA, the SEC and other government agencies or other disruptions at these agencies could hinder these agencies' ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. As of July 2020, and as reflected in an August 2020 guidance document last updated May 2021, utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, the FDA is either continuing to, on a case-by-case basis, conduct only mission critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. The FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace, and delays or setbacks are possible in the future. Should the FDA determine that an inspection is necessary for approval because available information raises concerns about the adequacy of the facility or site and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. Additionally, regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which

could have a material adverse effect on our business. Additionally, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, the FDA may not be able to continue its current pace and review timelines could be extended.

Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Results of earlier studies or clinical trials may not be predictive of future clinical trial results, and initial studies or clinical trials may not establish an adequate safety or efficacy profile for our product candidates to justify proceeding to advanced clinical trials or an application for regulatory approval.

The results of nonclinical and preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. The results of preclinical studies and clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size, demographics and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. For example, our STOP301 trial for Trudhesa primarily evaluated the safety and tolerability of Trudhesa against the patient's best previous migraine treatment. While exploratory efficacy endpoints were analyzed as part of the trial and were notable, the exploratory nature of the trial limits the interpretability of these results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. Even if early-stage clinical trials are successful, we may need to conduct additional clinical trials of our product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to obtain marketing approval for our product candidates would substantially harm our business, prospects, financial condition and results of operations.

Additionally, several of our past and planned clinical trials utilize an "open-label" trial design, including our STOP301 trial for Trudhesa. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates in clinical trials when studied in a controlled environment with a double-blind placebo or active control.

Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. For example, the most common adverse events in our STOP301 trial evaluating Trudhesa included nasal congestion, nausea, nasal discomfort and unpleasant taste. Moreover, we could in the future observe local toxicity in the nasal or olfactory epithelia.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- we may be unable to obtain regulatory approval for our product candidates;
- our clinical trials may be put on hold;
- regulatory authorities may withdraw approvals of our product candidates or require additional nonclinical studies or clinical trials;
- regulatory authorities may require additional warnings in the labeling;

- regulatory authorities may require us to implement a REMS;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could substantially increase commercialization costs.

Some of our clinical trials for our product candidates have been, and we may in the future conduct clinical trials for our product candidates, outside the United States, and the FDA or comparable foreign regulatory authorities may not accept data from such trials.

Some of our clinical trials for our product candidates have been conducted, and we may in the future choose to conduct one or more clinical trials, outside the United States. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice, or GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

If we fail to obtain regulatory approval in jurisdictions outside the United States, we will not be able to market our product candidates in those jurisdictions.

We intend to market Trudhesa and our other product candidates, if approved, in international markets either directly or through partnerships. Such marketing will require separate regulatory approvals in each jurisdiction and compliance with numerous and varying regulatory requirements. The approval procedures vary from jurisdiction to jurisdiction and may require additional testing that we are not required to perform to obtain regulatory approval in the United States. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign jurisdictions or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any foreign market. If we or any future partner are unable to obtain regulatory approval for our product candidates in one or more significant foreign jurisdictions, then the commercial opportunity for our product candidates, as well as our financial condition, will be adversely affected.

Even if we receive regulatory approval for our product candidates, they will be subject to ongoing regulatory requirements, which may result in significant additional expenses. Additionally, Trudhesa and our other product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for Trudhesa and our other product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed, or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. For example, under the Pediatric Research Equity Act, we are required to conduct certain juvenile animal and pediatric studies in accordance with the timelines set forth in our Trudhesa NDA approval letter. These studies will require significant resources. We cannot predict the outcome of these studies. In addition, the manufacturing processes, labeling, packaging, distribution, adverse event, or AE, reporting, storage, advertising, promotion and recordkeeping for any approved product will be subject to extensive and ongoing regulatory requirements. These

requirements include submissions of safety and other post-marketing information and reports, including reporting of certain adverse events, malfunctions, corrections and removals related to the POD device, registration, as well as continued compliance with cGMP for the drug products, the quality system regulation, or QSR, for medical devices and GCP for any clinical trials that we conduct post-approval.

Later discovery of previously unknown problems with an approved product, including AEs of unanticipated severity or frequency, or with manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- holds on clinical trials;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- fines, warning or untitled letters;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us, or withdrawal of product approvals;
- product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We may be subject to enforcement action by the FDA or other government agencies or competitor lawsuits or other claims, including litigation brought by the government, if we engage or are found to have engaged in improper promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including laws and regulations prohibiting marketing claims that promote the off-label use of our products or that omit material facts or make false or misleading statements about the safety or efficacy of our products. We are responsible for training our marketing and sales force not to promote our product candidates for off-label uses, but healthcare providers may use our products off-label as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. The FDA also could conclude that a claim is misleading if it determines that there are inadequate nonclinical and/or clinical data supporting the claim, or if a claim fails to reveal material facts about the safety or efficacy of our products. If the FDA determines that our promotional labeling or advertising materials promote an off-label use or make false or misleading claims, it could request that we modify our promotional materials or training content or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines and criminal penalties.

The FDA closely regulates the pre and post-approval marketing and promotion of drugs to ensure they are promoted and marketed in compliance with the FDCA and its implementing regulations and only for the approved indications and in a manner consistent with the approved labeling. For example, our labeling for Trudhesa does not include any of the data from the exploratory efficacy endpoints that we evaluated in our Phase 3 safety clinical trial or contain any efficacy claims based on the results of this study. If the FDA disagrees with our claims or approach to describing the efficacy results from any data deemed as unreliable or uninterpretable, including our exploratory efficacy analyses, in our promotional materials, it may take enforcement action against us. In addition, without conducting head-to-head clinical trials designed to investigate the clinical superiority of our product candidates to marketed products, we would not be able to make any such claims in our promotional materials. The FDA imposes stringent restrictions on manufacturers' communications and promotion of their products, including specific restrictions for promotions of products with Black Box Warnings. If we promote our product candidates in a manner inconsistent with the FDA-approved labeling or otherwise not in compliance with the FDCA or implementing regulations, we may be subject to enforcement action. Violations of the FDCA relating to improper promotion of prescription drugs may lead to warning letters, investigations, violations under federal and state healthcare fraud and abuse laws, including the False Claims Act, as well as state consumer protection laws.

It is also possible that other federal, state or foreign enforcement authorities might take action if they determine that our promotional or training materials promote an unapproved use or make false or misleading claims, which could result in significant fines or penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products or false or misleading claims, the FDA or another regulatory agency could disagree with the manner in which we advertise and promote our products. Violations of the FDCA may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which may lead to costly penalties and may adversely impact our business. Recent court decisions have impacted the FDA's enforcement activity regarding off-label promotion in light of First Amendment considerations; however, there are still significant risks in this area, in part due to the potential for False Claims Act exposure. Competitors may also object to our promotional claims, particularly with regard to clinical superiority to marketed products, which could lead to trade complaints to FDA or other actions related to unfair competition.

Many companies have also faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities. In addition, the government and private whistleblowers have pursued False Claims Act cases against pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. If we are found to have improperly promoted our products, we may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federally funded healthcare programs and potential liability under the federal False Claims Act and any applicable state false claims act. In addition, we may incur liability from claims initiated under the Lanham Act or other federal and state unfair competition laws with respect to how our products are marketed and promoted. Furthermore, the off-label use of our products may increase the risk of product liability claims. The scope of potential liability with respect to any such claims, enforcement actions, or lawsuits is uncertain, and we cannot assure you that we will not receive claims from competitors or other third parties or be subject to enforcement actions in the future from regulatory agencies. Moreover, threatened or actual government enforcement actions or lawsuits by third parties could generate adverse publicity, which could decrease demand for our products and require that we devote substantial resources that could be used productively on other aspects of our business.

Our relationships with health care professionals, institutional providers, principal investigators, consultants, potential customers and third-party payors are, and will continue to be, subject, directly and indirectly, to federal and state health care fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and privacy, data protection and data security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal and state health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. If we obtain FDA approval for any of our product candidates and begin commercializing those product candidates in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to laws of the federal government and state governments in which we conduct our business relating to privacy, data protection and data security with respect to patient information. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation

of any good, facility, item or service for which payment may be made, in whole or in part, under a federal health care program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from a federal health care program, such as Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, health care benefits, items or services relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered health care providers, health plans, and health care clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician's family has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- the federal Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, or the ACA, and its implementing regulations require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare & Medicaid Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, including ownership and investment interests held by physicians and their immediate family members; effective January 1, 2022, reporting on payments and transfers of value made in the previous year to covered recipients will be expanded to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, changed by the ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our product candidates, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);
- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and
- state law equivalents and adjuncts to many of the above federal laws, such as anti-kickback, false claims, consumer protection, unfair competition, and privacy and data security laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submission of claims involving any of our product candidates or related health care services for reimbursement by any third-party payor, including public and commercial insurers; state laws that require biotech companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensation and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business or increase enforcement scrutiny of our activities); state laws regarding the reporting of certain pricing information; and state laws

governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects and obligations.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the laws and regulations mentioned above, including reporting requirements detailing interactions with and payments to healthcare providers, and requirements in Europe and other jurisdictions relating to privacy, data protection and cybersecurity, among other foreign laws. In addition to health information privacy, data security, and data protection laws that apply to some of the patient data we hold, other privacy, data security and data protection laws may also apply to such data, as well as to the personal data of our employees and other individuals generally. Many of these laws governing privacy, data protection and cybersecurity differ from each other in significant ways and may not have the same effects or obligations, thus complicating compliance efforts. We expect to incur increased costs of compliance with such laws and regulations as they continue to evolve, as well as the increased risk of regulatory investigations, enforcement actions, and other claims and litigation, with the potential for significant fines, penalties, and other liabilities in the event of actual or alleged noncompliance. Any of these could adversely affect our business, financial condition, and results of operations.

The ACA, among other things, amended the intent standard of the federal Anti-Kickback Statute and criminal health care fraud statutes to a stricter standard such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, imprisonment, loss of eligibility to obtain approvals from the FDA, qui tam actions, lawsuits, government investigations, exclusion from participation in government contracting, healthcare reimbursement, or other federal or state government healthcare programs, including Medicare and Medicaid, corporate integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

The impact of recent health care reform legislation and other changes in the health care industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow on biologic products, (ii) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual nondeductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, apportioned among these entities according to their market share in certain government healthcare programs, (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs and therapeutic biologics to be covered under Medicare Part D, which has since been increased to 70% by the Bipartisan Budget Act of 2018, or the BBA, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such

research and (ix) established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act of 2017, or the Tax Reform Act, among other things, included a provision that repealed, effective January 1, 2019, the tax based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, in January 2021, President Biden issued an executive order to initiate a special enrollment period to allow people to obtain health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021, and instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, among others. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the ACA and our business. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on certain high-cost employer-sponsored insurance plans and the medical device excise tax, and effective January 1, 2021, also eliminates the health insurer tax. The BBA, among other things, also amended the ACA, effective January 1, 2019, by increasing from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, CMS published a final rule that would give states greater flexibility, effective January 1, 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there have been several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In 2020, the HHS and the CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. Additionally, the Trump and Biden administrations have both issued executive orders intended to favor government procurement from domestic manufacturers. In January 2021, the Biden administration issued a "regulatory freeze" memorandum that directs department and agency heads to review new or pending rules of the prior administration. It is unclear whether these new regulations will be withdrawn or when they will become fully effective under the current administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the current administration on us and the pharmaceutical industry as a whole is unclear. We expect additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. It is unclear to what extent these new regulations will be implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements.

Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration. Such reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize Trudhesa and our other product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

We expect to transition the POD device used in the INP105 and INP107 clinical trials to a commercial stage POD device for pivotal clinical trials and commercialization, which may be unsuccessful or costly.

While we used for our Trudhesa STOP301 trial the version of our POD device that we intend to use for commercialization, the version of our POD devices used in the initial clinical trials for INP105 and INP107 will need to be further refined for use in later-stage clinical trials and to enable larger scale manufacturing and distribution, if the INP105 and INP107 candidates receive regulatory approvals. We expect to transition these clinical-stage POD devices to commercial stage POD devices prior to pivotal clinical trials and commercialization. The development work on the commercial stage devices for INP105 and INP107 is ongoing. We cannot be certain that the transition from the clinical stage POD device to the commercial stage POD device will be successful or be completed on time. If we are unable to complete the transition in a timely and cost-effective manner, our clinical trials and commercialization efforts may be harmed.

Risks Related to Commercialization of Trudhesa and Our Other Product Candidates

Our future commercial success depends upon attaining significant market acceptance of Trudhesa and our other product candidates, if approved, among physicians, patients, health care payors and others in the medical community necessary for commercial success.

Even if we obtain regulatory approval for INP105, and INP107 or any other product candidate that we may develop or acquire in the future, Trudhesa and these other product candidates may not gain market acceptance among physicians, health care payors, patients and the medical community. There are several approved acute treatments for migraine currently on the market, including triptans, ditans, calcitonin gene-related peptides antagonists, or gepants, lasmiditan and alternative formulations of DHE, such as Migranal, which is administered intranasally. All of these will be competitive with Trudhesa and our level of market acceptance of Trudhesa for the acute treatment for migraine may be lower than we expect. Market acceptance of Trudhesa or any other approved product candidates depends on a number of factors, including:

- the efficacy and safety of our product candidates;
- perceived advantages of our product candidates over alternative treatments, such as oral, IM and IV formulations;
- the indications for which the product candidates are approved and the labeling approved by regulatory authorities for use with the product candidates, including any warnings, limitations or contraindications contained in a product's approved labeling;
- acceptance by physicians and patients of the product candidate as a safe and effective treatment;
- the cost, safety and efficacy of treatment in relation to alternative treatments, including generic versions of the product candidates;
- the extent to which our product candidates are included on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities for the product candidates;
- relative convenience and ease of administration of the product candidates;
- the prevalence and severity of adverse side effects;
- the timing of market introduction of competitive product;

- restrictions on the distribution of our product candidates;
- the effectiveness of our sales and marketing efforts;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

Market acceptance is critical to our ability to generate significant revenue and become profitable. Trudhesa and any other product candidate that is approved and commercialized, may be accepted in only limited capacities or not at all. If Trudhesa or any other approved product candidates are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

The market for Trudhesa and our other product candidates may not be as large as we expect.

Our estimates of the potential market opportunity for Trudhesa and our other product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys, including surveys commissioned by us. These assumptions include the size of our target populations, the prevalence and incidence of each of our target indications, the number of patients receiving current treatment, the percentage of patients unsatisfied with the current treatments, the number of diagnosed but untreated patients, the compliance and adherence of patients in our target populations, the number of treatment centers and prescribing physicians and the percentage of payer acceptance. While we believe that our internal assumptions are reasonable, if any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of our potential market opportunity. If the actual market for any of our product candidates is smaller than we expect, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

In addition, the FDA has required labeling restrictions on the patients and uses of Trudhesa and we anticipate may require similar labeling restrictions on our other product candidates that may be approved by the FDA, including but not limited to contraindications for use in certain populations. For example, upper nasal cavity drug delivery may not be appropriate for use by patients with certain pre-existing conditions, such as chronic rhinitis, seasonal allergies or anatomical nasal obstruction.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

While certain of our executives have commercialization expertise, we do not have a sales or marketing infrastructure. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales and marketing organization.

We are building a focused sales and marketing infrastructure to market Trudhesa and will potentially expand our focused sales and marketing infrastructure to market our other product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, including failure to receive marketing approval from the FDA, we would have prematurely or unnecessarily incurred these commercialization expenses. We may also inaccurately estimate the number of representatives needed to build our sales force, which may result in unnecessary expense or the inability to scale as quickly as needed. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize Trudhesa and our other product candidates, if approved, on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any product candidates;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors for our product candidates;
- the inability to price our product candidates at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our product candidates to segments of the patient population;

- the lack of complementary product candidates to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates outside of the United States or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Problems related to large-scale commercial manufacturing could cause delays in product launches, an increase in costs or shortages of product candidates.

Manufacturing finished drug products, especially in large quantities, is complex. The commercialization of Trudhesa will require several manufacturing steps and may involve complex techniques to assure quality and sufficient quantity, especially as the manufacturing scale increases. Additionally, if our other product candidates receive regulatory approval, they will also require several manufacturing steps and may involve complex techniques to assure quality and sufficient quantity, especially as the manufacturing scale increases. Trudhesa and our other product candidates will need to be made consistently and in compliance with a clearly defined manufacturing process pursuant to FDA regulations. Accordingly, it will be essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including obtaining materials, filling, labeling, packaging, storage, shipping, quality control and testing, may result in lot failures, delay in the release of lots, product recalls or spoilage. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs. We may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and cause us to fail to satisfy contractual commitments, lead to delays in our clinical trials or result in litigation or regulatory action. Such actions would hinder our ability to meet contractual obligations and could cause material adverse consequences for our business.

Reimbursement for any approved products may be limited or unavailable, which could make it difficult for us to sell our product candidates profitably.

In both domestic and foreign markets, sales of any of Trudhesa and our other product candidates, if approved, will depend, in part, on the extent to which the costs of our product candidates will be covered by third-party payors, such as government health care programs, commercial insurance and managed health care organizations. These third-party payors decide which drugs will be covered and establish reimbursement levels for those drugs. The containment of health care costs has become a priority of foreign and domestic governments as well as private third-party payors. The prices of drugs have been a focus in this effort. Governments and private third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. Cost-control initiatives could cause us to decrease the price we might establish for product candidates, which could result in lower than anticipated product revenues.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective relative to other alternatives, including generic products; and
- neither experimental nor investigational.

Adverse pricing limitations may hinder our ability to recoup our investment in our existing and any future product candidates, even if such product candidates obtain marketing approval.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our product candidates to the payor. Further, there is significant uncertainty related to third-party payor coverage and reimbursement of newly approved product candidates, including our product candidates if they are approved. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, Trudhesa and our other product candidates. If reimbursement is not available or is available only to limited levels, we may not

be able to successfully commercialize certain of our product candidates. In addition, in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new product candidates. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved product candidates, which in turn will put pressure on pricing.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, including member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and other countries and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

We face substantial competition, which may result in others discovering, developing or commercializing product candidates before, or more successfully, than we do.

The development and commercialization of new and improved pharmaceutical products is highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research development of product candidates which may target the same markets as our product candidates. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates within those markets. We expect any future product candidates we develop and commercialize on our own or with our strategic partners, if approved, to compete with existing and leading products in the market on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects experienced and convenience of administration and drug delivery.

For our product candidates, we are aware of the following competing efforts:

- ***TRUDHESA***. Approved acute treatments for migraine include triptans, ditans, gepants, lasmiditan and alternative formulations of DHE, such as Migranal, which is administered intranasally. Some of these competitor products have been launched. Some of these competitors are also developing product candidates that utilize alternative routes of administration, including Biohaven Pharmaceuticals, Inc., Amneal Pharmaceuticals, Inc., Satsuma Pharmaceuticals, Inc. and Zosano Pharma Corporation, whose product candidates use nasal pumps or other drug delivery technologies.
- ***INP105***. While there are no FDA-approved acute treatments for agitation and aggression in ASD, commonly prescribed treatments include mostly atypical (second generation) antipsychotics. These can include risperdone (Risperdal), olanzapine (Zyprexa), quetiapine (Seroquel), aripiprazole (Abilify), ziprasidone (Geodon) and others.
- ***INP107***. Approved treatments for the symptoms of OFF episodes in Parkinson’s include carbidopa/levodopa (both short and long-acting oral forms), MAO-B inhibitors, COM-T inhibitors, dopamine agonists, amantadine such as Gocovri, apomorphine and inhaled levodopa, such as Inbrija. In addition, there are several product candidates under development by pharmaceutical companies such as Eli Lilly & Co., Intec Pharma Ltd. and AbbVie Inc. Some of these product candidates also utilize alternative routes of administration, such as Sunovion Pharmaceuticals, Inc., whose product candidate uses a sublingual film, and Acorda Therapeutics, Inc. whose product candidate uses a dry powder inhaler.

One or more of our competitors may utilize their expertise in other methods of pharmaceutical drug delivery to develop and obtain approval for upper nasal cavity delivery products that may compete with our product candidates. These competitors may include Aegis, Optinose and other smaller pharmaceutical companies. Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have had to date. Our ability to compete effectively will depend, in part, on the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position, the safety and effectiveness of our product candidates, the ease with which our product candidates can be administered and the extent to which patients accept relatively new routes of administration. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any product candidates we may develop. Competitive products may reduce the demand and price for any product candidates we develop, making them obsolete or noncompetitive before we recover the expense of

developing and commercializing such product. Our competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

We rely entirely on third parties for the manufacturing of Trudhesa and our other product candidates that we develop for nonclinical studies and clinical trials and expect to continue to do so for commercialized products. If we encounter difficulties in negotiating manufacturing and supply agreements with third-party manufacturers and suppliers of our POD device and the active ingredients in Trudhesa , INP105 and INP107, our ability to commercialize our other product candidates, if approved, would be impaired.

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturing organizations, or CMOs, and suppliers, including in some cases single-source suppliers, who assist in the production, assembly, test, validation, supply, storage and distribution of our drug-device combination product candidates in our clinical trials, and we do not control their activities. While we have developmental and commercial supply agreements in place with some of our key suppliers, we may not be able to obtain terms that are favorable to us or enter into commercial manufacturing and supply agreements at all with other necessary third parties. If we are unable to enter into such agreements on commercially reasonable terms, our ability to commercialize Trudhesa and our other product candidates, if approved, would be impaired, and our business, financial condition and results of operations would be materially adversely affected.

If and when product sales for Trudhesa, or other product candidates, if approved, grow, Trudhesa and our other product candidates will require production processes to be scaled up. We will be dependent on external manufacturers and suppliers to ensure that their manufacturing processes can be scaled up adequately such that we are able to supply the market. If any of our key suppliers are unable or unwilling to scale up production, our product candidates would be impaired, and our business, financial condition and results of operations would be materially adversely affected.

Additionally, we currently have no plans to build our own clinical or commercial scale manufacturing facility. Should any of our product candidates receive approval, we would lack the resources and expertise to manufacture and test, on a commercial scale, the technical performance of our POD device and the active ingredients, and would need to incur significant expense to develop and acquire such expertise internally or partner with a third-party who possesses such expertise.

We rely on third parties to conduct nonclinical studies and clinical trials, and if they do not properly and successfully perform their obligations to do so, we may not be able to obtain regulatory approvals for our product candidates.

We rely on CROs and other third parties to assist in managing, monitoring and otherwise carrying out nonclinical and clinical trials for our product candidates. We compete with many other companies for the resources of these third parties. Any disruption in supply from any supplier or manufacturing location, including on account of the COVID-19 pandemic, could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. Further, the third parties on whom we rely generally may terminate their engagements at any time. Having to enter into alternative arrangements would delay development and commercialization of our product candidates.

The FDA and comparable foreign regulatory authorities require compliance with regulations and standards, including GCP, for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct many of our clinical trials, they are not our employees, and we are responsible for ensuring that each of these clinical trials is conducted in accordance with our general investigational plan, protocol and other requirements. Our reliance on these third parties for clinical research and development activities will reduce our control over these activities but will not relieve us of our responsibilities.

If these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our nonclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis, or at all.

If we encounter issues with our CMOs or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply product candidates.

We currently depend on third parties to manufacture and supply our POD device, the active pharmaceutical ingredients and final formulations in our product candidates. Although we could obtain each of these components from other third-party suppliers, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for each such component, which could be costly and cause significant delays. Each of our current manufacturing and supply agreements include limitations on our

ability to utilize alternative manufacturers or suppliers during the terms of the agreements, which impairs our ability to prepare in advance for any future manufacturing and supply shortages or quality issues.

In addition, some of our suppliers conduct their manufacturing operations for us at a single facility. Unless and until we qualify additional facilities, we may face limitations in our ability to respond to manufacturing and supply issues. For example, if regulatory, manufacturing or other problems require one of these manufacturers or suppliers to discontinue production at their respective facility, or if the equipment used for the production of our POD device or the active ingredients in these facilities is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer or supplier to provide components or the active pharmaceutical ingredients needed for our product candidates, or to manufacture our product candidates may be significantly impaired. In the event that these parties suffer a temporary or protracted loss of our facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer or supplier, as applicable, as an alternate manufacturer or source for the respective component before any components manufactured by such manufacturer or by such supplier could be sold or used. To do so, we would need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize any of our approved products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture the product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies before implementing the change for our clinical supply for use in clinical trials or for commercial supply of any approved product. We may be unsuccessful in demonstrating the comparability of supplies before and after a manufacturing change, which could require the conduct of additional clinical trials and result in a delay or disruption in our clinical development plan or our ability to commercialize any approved product.

Any production shortfall that impairs the supply of our POD device or the active ingredients or any of these components could negatively impact our ability to complete clinical trials, obtain regulatory approval and commercialize our product candidates. If our product candidates receive approval, a product shortfall could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for our product candidates, which could materially and adversely affect our product sales and operating results.

If third-party manufacturers, wholesalers and distributors fail to perform as expected, or fail to devote sufficient time and resources to our product candidates, our clinical development may be delayed, our costs may be higher than expected or our product candidates may fail to be approved.

Our reliance on third-party manufacturers, wholesalers and distributors exposes us to the following risks, any of which could delay FDA approval of our product candidates and commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;
- our wholesalers and distributors could become unable to sell and deliver our product candidates for regulatory, compliance and other reasons;
- our CMOs, wholesalers and distributors could breach or default on their agreements with us to meet our requirements for commercialization of our product candidates;
- our CMOs, wholesalers and distributors may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell and distribute our product candidates and we may incur additional cost;
- our CMOs, wholesalers and distributors may misappropriate our proprietary information; and
- if our CMOs, wholesalers and distributors were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay our commercial programs.

For example, we identified increased levels of impurities in some drug vials of certain drug lots used in our Trudhesa STOP301 trial. Vials from those drug lots were removed from the trial and we conducted a root cause investigation, identifying the likely root cause as long stoppages in the production of two lots. We have not identified any safety issues in our Phase 3 clinical trials related to exposure to the increased levels of impurity. We had a pre-NDA meeting with the FDA on this topic and described our investigation and response to the issue in the NDA submission. At that time, the FDA did not concur that the investigation had adequately identified the root cause of the presence of impurities. While we have conducted additional investigations that have led us to believe we identified the root cause and we have worked with our CMO to avoid those conditions in future production runs, there is no guarantee that the

FDA will agree that our subsequent investigations have adequately identified the root cause, or that our corrective and preventive actions have sufficiently remediated the issue.

Our reliance on third parties reduces our control over our product candidate development activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and QSR, and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or QSR or maintain a compliance status acceptable to the FDA or other regulatory authorities or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, our third-party manufacturers will be subject to periodic inspections by the FDA and other regulatory authorities, and failure to comply with cGMP or QSR could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including request a recall or seize product candidates, total or partial suspension of production, suspension of clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of product candidates, injunction, imposing civil penalties or pursuing criminal prosecution.

Additionally, as we scale up manufacturing of our product candidates and conduct required stability testing, issues may arise involving product-packaging and third-party equipment malfunctions. These issues may require refinement or resolution in order to proceed with commercial marketing of our product candidates. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in our product or delivery devices could result in increased scrutiny by regulatory authorities, delays in our regulatory approval process, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize product candidates, negatively impacting our operating results.

We continue to strategically evaluate and, as deemed appropriate, we may enter into partnerships in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies, although there is no guarantee we will be able to enter into these agreements if we elect to do so. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully identify and work with partners, potential partners must view our product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available product candidates for licensing by other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product candidates could delay the development and commercialization of such candidates and reduce their competitiveness even if they reach the market. In addition, we have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively or create sufficient sales.

If we fail to establish and maintain strategic partnerships related to our product candidates, we will bear all of the risk and costs related to the development of any such candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise, such as regulatory expertise, for which we have not budgeted. This could negatively affect the development of any unpartnered product candidate.

Risks Related to Our Intellectual Property

If we are not able to obtain and enforce patent protection for our technologies or product candidates, development and commercialization of our technology and product candidates may be adversely affected.

Our success depends in part on our ability to obtain, maintain, protect and enforce patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, relating to our product candidates, our technology such as our proprietary POD nasal drug delivery platform, and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. As of September 30, 2021, we solely owned six issued U.S. patents, 14 pending U.S. patent applications, 32 issued foreign patents, 74 pending foreign patent applications, and two pending international applications that cover our marketed product candidates, development product candidates, and our proprietary POD nasal drug delivery platform. We may not be able to apply for patents on certain aspects of our technology and our product candidates in a timely fashion or at all. Further, we may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation,

filing and prosecution of any patent applications that we license from third parties, or the ability to maintain the rights to patents licensed to third parties, and should we decide to license any of our patents to third parties in the future, we may not retain sufficient rights to prosecute and enforce such patents. Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing product candidates and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our technology and our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and pharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary product candidates and drug delivery system. Accordingly, despite our efforts, we may be unable to prevent third parties from infringing upon or misappropriating our intellectual property. While we will endeavor to try to protect our technology and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and sometimes unpredictable. The failure to adequately protect our intellectual property and other proprietary rights could materially harm our business.

We may be required to spend significant resources to monitor and protect our intellectual property rights. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. Any patents that are issued may subsequently be invalidated or otherwise limited, allowing other companies to develop offerings that compete with our offerings, which could adversely affect our competitive business position, business prospects and financial condition. In addition, issuance of a patent does not guarantee that we have a right to practice the patented invention. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action before patent offices for a given period after allowance or grant, during which time third parties can raise objections against such initial grant, or in court. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

In addition, there can be no assurance that:

- others will not or may not be able to make, use or sell upper nasal cavity product candidates that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own;
- we or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own;
- we, or our existing or future collaborators, are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party will not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed;
- any issued patents that we own or have licensed will provide us with any competitive advantages, or will not be challenged by third parties;

- we may develop additional proprietary technologies that are patentable;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

If we, our licensor or collaborators fail to maintain the patents and patent applications covering our technology or product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our technology and our product candidates, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, we cannot be certain that such agreements have been entered into with all relevant parties. In addition, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Other companies or organizations may challenge our or our licensor's patent rights or may assert patent rights that prevent us from developing and commercializing our product candidates.

The issued patents and pending patent applications in the United States and in key markets around the world that we own or license claim many different devices, compositions and methods, including processes relating to the discovery, development, manufacture and commercialization of upper nasal cavity drug delivery. As the field of upper nasal cavity drug delivery continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete.

We may not be able to protect our intellectual property rights throughout the world.

Obtaining a valid and enforceable issued or granted patent covering our technology in the United States and worldwide can be extremely costly, and our or our licensor's or collaborators' intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than in the United States. In jurisdictions where we or our licensor or collaborators have not obtained patent protection, competitors may seek to use our or their technology to develop their own products and further, may export otherwise infringing products to territories where we or they have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future product candidates in jurisdictions where we do not have issued or granted patents or where our or our licensor's or collaborators' issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly relating to pharmaceuticals. This could make it difficult for us or our licensor or collaborators to prevent the infringement of our or their patents or marketing of competing products in violation of our or their proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our and our licensor's or collaborators' efforts and attention from other aspects of our business, could put our and our licensor's or collaborators' patents at risk of being invalidated or interpreted narrowly, and our and our licensor's or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensor or

collaborators. We or our licensor or collaborators may not prevail in any lawsuits that we or our licensor or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that depending on the country, various scopes of patent protection may be granted on the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensor or collaborators encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensor or collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

We, our collaborators, or any future strategic partners may need to resort to litigation to protect or enforce our patents or other proprietary rights, all of which could be costly, time consuming, delay or prevent the development and commercialization of our technology or product candidates, or put our patents and other proprietary rights at risk.

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that an individual connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a materially misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

Intellectual property rights of third parties could adversely affect our ability to commercialize our technology or our product candidates, and we, our licensor or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our technology or our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

We, our collaborators, or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, post grant review and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. We have previously received communications from third parties claiming that our technology infringes on their patents. While we do not believe that these claims have merit, we cannot be certain that these third parties would not pursue infringement claims against

us. There are issued and pending patents that might claim aspects of our technology and our product candidates, and modifications that we may need to apply to our technology or our product candidates. Thus, it is possible that one or more individuals or organizations will hold patent rights to which we will need a license. If those individuals or organizations refuse to grant us a license to such patent rights or refuse to grant us a license on reasonable terms, we may not be able to market product candidates or perform research and development or other activities covered by these patents which could have a material and adverse effect on our business, financial condition, results of operations and prospects. We are obligated under certain of our license and collaboration agreements to indemnify and hold harmless our licensor or collaborators for damages arising from intellectual property infringement by us. If we, our licensor or collaborators, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have infringed willfully. In addition, we, our licensor or collaborators, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market our technology or our product candidates, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation could divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

Because the upper nasal cavity therapeutics landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our technology or our product candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize our technology or our product candidates until such patents expire or unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents held by third parties of which we are not aware that, if found to be valid and enforceable, could be alleged to be infringed by our POD nasal drug delivery platform and related technologies and product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our POD nasal drug delivery platform and related technologies and product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, including potentially treble damages and attorneys' fees for willful infringement, and we may be forced to abandon our technology or our product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technology, our product candidates or the use of our product candidates. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our technology or our product candidates that are held to be infringing. We might, if possible, also be forced to redesign our technology or our product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights of third parties could delay the development timeline with respect to one or more of our product candidates.

Trudhesa includes a prior-approved formulation of our active pharmaceutical ingredient and our INP105 and INP107 product candidates include prior-approved active pharmaceutical ingredients. We are not aware of any unexpired patents that cover these active pharmaceutical ingredients, and there are no unexpired patents or regulatory exclusivities listed on the FDA Orange Book for the formulation we are using in Trudhesa. However, it is possible that one or more individuals or organizations will hold patent rights to which we will need to obtain a license. If those individuals or organizations refuse to grant us a license to such patent rights or refuse to grant us a license on commercially reasonable terms, our development timeline with respect to one or more of our product candidates may be materially and adversely delayed.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that we or our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or their former employers. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our technology or our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Patent terms may be inadequate to protect our competitive position on our technology or our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our technology or our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm or rely on our outside counsel to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other ex-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. For example, the decision by the U.S. Supreme Court in Association for Molecular Pathology v. Myriad Genetics, Inc. precludes a claim to a nucleic acid having a stated nucleotide sequence that is identical to a sequence found in nature and unmodified. We currently are not aware of an immediate impact of this decision on our patents or patent applications because we are developing product candidates that contain modifications that we believe are not found in nature. However, this decision has yet to be unambiguously interpreted by courts and by the USPTO. We cannot assure you that the interpretations of this decision or subsequent rulings will not adversely impact our patents or patent applications. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. A third party that files a patent application in the USPTO after March 2013, but before we do, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, and results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Employee Matters, Managing Growth and Other Risks Related to Our Business

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers, manufacturers and other third parties. Future growth will impose significant added responsibilities on members of our management. Our future financial performance and our ability to commercialize Trudhesa and our other product candidates, if approved, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company or disrupt our operations.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.

We are highly dependent on members of our senior management, including Adrian Adams, our President and Chief Executive Officer, John Hoekman, Ph.D., Chief Technology and Development Officer and one of our founders, John Leaman, M.D., our Chief Financial Officer, Leonard S. Paolillo, our Chief Commercial Officer, and Stephen Shrewsbury M.B. ChB., our Chief Medical Officer. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. Also, each of these persons may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, including our scientific co-founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market, or Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We will need to hire additional accounting, finance and other personnel and make further investments in processes and systems in connection with these efforts. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by

regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are not currently required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company or a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Employees may also misappropriate information in violation of applicable insider trading laws, which could also seriously harm our reputation even if we are not deemed to be at fault. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the commercial sale of Trudhesa and any other approved product candidate, as well as from clinical testing of our product candidates. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- injury to our reputation;
- decreased demand for our product candidates or products that we may develop;
- withdrawal of clinical trial participants;
- costs to defend the related litigations;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;

- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to successfully commercialize Trudhesa and our other product candidates, if approved; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop. We currently carry product liability insurance covering the commercial sale of Trudhesa and our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, we could prevent or inhibit the development and commercial production and sale of our product candidates, which could adversely affect our business, financial condition, and results of operations.

The security of the information technology systems used in our business may be compromised, and confidential information, including non-public personal information, could be improperly disclosed.

Our information technology systems, and those of our contractors, service providers and consultants, may be vulnerable to physical or electronic intrusions, computer viruses or other attacks, as well as employee, vendor, or contractor errors or malfeasance. As part of our business, we and our contractors and consultants maintain large amounts of confidential information, including non-public personal information on patients and our employees. Breaches in security and other information security events and incidents, including from ransomware, other malicious code, and other cyberattacks, could result in interruption to our systems and operations, or those of our contractors, consultants or our respective service providers, and the loss, unavailability, and unauthorized modification, use, acquisition or disclosure of information, including information subject to intellectual property protection or for which the loss or other compromise of such information may lead to the loss of intellectual property protection. Any such breach or other incident may result in significant costs to remediate and otherwise respond, including efforts to analyze, correct, eliminate, remediate or work around deficiencies in our systems or our security measures, recover and validate data, and to address any applicable legal or contractual obligations. Further, any actual or perceived breach in security or security incident may result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, delays in regulatory filings and approvals, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. Like many businesses, we have been in the past, and may again be in the future, subject to phishing attacks. In 2018 we experienced a successful phishing attack. While we were able to swiftly contain and remediate this incident, without a material impact to our business, there can be no assurances that we will be able to defend against or successfully remediate any such attacks that may occur in the future. Further, companies have experienced an increase in phishing and social engineering attacks from third parties, including in connection with the COVID-19 pandemic. Also, due to the COVID-19 pandemic, the majority of our employees are working remotely. As a result, we may have increased cybersecurity and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we have implemented IT controls to reduce the risk of a cybersecurity or data security breach or incident, there is no guarantee that these measures will be adequate to safeguard all systems, especially with an increased number of employees working remotely. While we expect to implement and maintain appropriate information security policies and systems in order to prevent unauthorized loss, unavailability, modification, use or disclosure of confidential information, including non-public personal information and other information relating to individuals, there can be no assurance that any such loss, unavailability, modification, use or disclosure will not occur. We incur significant costs in an effort to detect and prevent security breaches and other security-related incidents and we expect our costs will increase as we make improvements to our systems, policies and processes to prevent further breaches and incidents. In the event of a future breach or incident, we could be required to expend additional significant capital and other resources in an effort to prevent further breaches or incidents, which may require us to divert substantial resources. Moreover, we could be required or otherwise find it appropriate to expend significant capital and other resources to respond to, notify third parties of, and otherwise address the incident or breach and its root cause. Each of these could require us to divert substantial resources.

While we maintain insurance with respect to cybersecurity, our insurance may be insufficient to cover all liabilities incurred by us in connection with any privacy or cybersecurity incidents. We also cannot be certain that any insurance coverage will be adequate for data handling or data security liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results and reputation.

If we acquire complementary business or technologies in the future, we may be unable to integrate such acquired businesses and technologies successfully or fail to achieve the expected benefits.

Although we have not made any acquisitions to date, our business strategy in the future may include acquiring other complementary therapies, products, technologies or businesses. We also may enter into relationships with other businesses to expand our domestic and international operations. An acquisition, investment, or business relationship may result in unforeseen operating difficulties and expenditures. In particular, we may encounter difficulties assimilating or integrating the businesses, therapies, technologies, products, services, personnel or operations of the acquired companies, particularly if the key personnel of the acquired companies choose not to work for us. Acquisitions may also disrupt our business, divert our resources and require significant management attention that would otherwise be available for the development of our business. Moreover, the anticipated benefits of any acquisition, investment or business relationship may not be realized or we may be exposed to unknown liabilities.

Negotiating these transactions can be time consuming, difficult, and expensive, and our ability to close these transactions may often be subject to approvals that are beyond our control. Consequently, these transactions, even if undertaken and announced, may not close. Even if we do successfully complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, and any acquisitions we complete could be viewed negatively by our customers, securities analysts and investors.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused losses incurred in taxable years beginning on or prior to December 31, 2017, will carry forward to offset future taxable income, if any, until such unused losses expire. Under the Tax Reform Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses is limited to 80% of current year taxable income in taxable years beginning after December 31, 2020. As a result, our net operating loss carryforwards generated in taxable years beginning on or before December 31, 2017, may expire prior to being used, and the deductibility of our net operating loss carryforwards generated in taxable years beginning after December 31, 2017 in taxable years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to the Tax Reform Act or the CARES Act. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code) if we undergo, or have undergone, an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future. If we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Changes in U.S. tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, the CARES Act was enacted, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our common stock.

Risks Related to Our Common Stock

The market price of our common stock may be volatile.

The market price of our common stock has been and may continue to be volatile. The market price for our common stock may be influenced by many factors, including the other risks described in this section and the following:

- receipt of marketing approval for our other product candidates;
- results of nonclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- introductions and announcements of new product candidates by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;
- the success of competitive products or technologies;
- actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the life sciences and pharmaceutical sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- the concentration in ownership of our common stock;
- changes in accounting principles;
- potential litigation or the threat thereof;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the markets for pharmaceutical and medical device stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of these companies, including as a result of the COVID-19 pandemic. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of September 30, 2021, our executive officers, directors and their respective affiliates owned a substantial portion of our voting stock. As a result, these stockholders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We are an "emerging growth company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in the annual reports.

We could be an emerging growth company until December 31, 2026, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

Anti-takeover provisions in our restated certificate of incorporation and our restated bylaws and under Delaware or Washington law could make an acquisition of our business, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Moreover, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a "target corporation" from engaging in any of a broad range of business combinations with any stockholder constituting an "acquiring person" for a period of five years following the date on which the stockholder became an "acquiring person." Any of these provisions of our charter documents or Delaware or Washington law could, under certain circumstances, depress the market price of our common stock.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders and our restated bylaws designate federal district courts as the sole and exclusive forum for actions under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or agents.

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under the DGCL: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

Our restated bylaws also provide that the federal district courts of the United States of America is the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation or restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

General Risk Factors

Natural disasters, catastrophic events and calamities including epidemics and pandemics may disrupt our business.

Natural disasters or other catastrophic events may damage or disrupt our operations and thus could harm our business. For example, our headquarters are located in Seattle, Washington, an earthquake-prone area. A natural disaster or catastrophic event in Seattle could interrupt our operations and impair access to internal systems, documents, and materials critical to the operation and growth of our business.

Further, occurrences of epidemics or pandemics, depending on their scale, may result in damage to the national and local economies within our geographic area. Global economic conditions may be disrupted by widespread outbreaks of infectious or contagious diseases, and such disruption may adversely affect clinical development plans. See "Risk Factors—*The outbreak of COVID-19, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our planned clinical trials.*"

As we grow, the need for business continuity planning and disaster recovery plans will become increasingly important. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. If we are unable to develop adequate plans to ensure that our business functions continue to operate during and after a disaster, and successfully execute on those plans in the event of a disaster or emergency, our business could be harmed.

We and our CMOs must comply with environmental, health and safety laws and regulations, and failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and our CMOs are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. We could also incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We are uninsured for third-party injury from contamination.[3]

Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our CMOs, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our product candidates, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our common stock, our stock price and trading volume could decline.

The trading market for our common stock can be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our nonclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

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

(a) Unregistered Sales of Equity Securities

None.

(b) Use of Proceeds from Public Offering of Common Stock

On April 27, 2021, we completed our IPO and issued 5,333,334 shares of our common stock at an initial offering price of $15.00 per share. We received net proceeds from the IPO of approximately $72.0 million, after deducting underwriting discounts and commissions of approximately $5.6 million and offering expenses of approximately $2.4 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. Wedbush PacGrow, Guggenheim Securities, LLC and Cowen and Company, LLC acted as book-running managers for the IPO.

Shares of our common stock began trading on The Nasdaq Global Select Market on April 23, 2021. The offer and sale of the shares were registered under the Securities Act on a registration statement on Form S-1 (Registration No. 333-254999), which was declared effective on April 22, 2021.

There has been no material change in the planned use of proceeds from our IPO as described in the registration statement on Form S-1.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit No	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
4.1	Warrant to Purchase Common Stock issued by the Company on July 2, 2021, in favor of Silicon Valley Bank, pursuant to the Security and Loan Agreement, dated as of July 2, 2021, by and between the Registrant and Oxford Finance LLC and Silicon Valley Bank.	10-Q	001-40353	4.3	August 16, 2021	
4.2	Warrant to Purchase Common Stock issued by the Company on July 2, 2021, in favor of Oxford Finance, LLC pursuant to the Security and Loan Agreement, dated as of July 2, 2021, by and between the Registrant and Oxford Finance LLC and Silicon Valley Bank.	10-Q	001-40353	4.4	August 16, 2021	
4.3	Warrant to Purchase Common Stock issued by the Company on September 30, 2021, in favor of Oxford Finance, LLC pursuant to the Security and Loan Agreement, dated as of July 2, 2021, by and between the Registrant and Oxford Finance LLC and Silicon Valley Bank.					X
4.4	Warrant to Purchase Common Stock issued by the Company on September 30, 2021, in favor of Silicon Valley Bank, pursuant to the Security and Loan Agreement, dated as of July 2, 2021, by and between the Registrant and Oxford Finance LLC and Silicon Valley Bank.					X
10.1	Security and Loan Agreement, dated as of July 2, 2021, by and between the Registrant and Oxford Finance LLC and Silicon Valley Bank.	10-Q	001-40353	10.4	August 16, 2021	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
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).					X

101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, is not deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.

Impel Neuropharma, Inc.

Date: November 15, 2021

By: /s/ Adrian Adams

Adrian Adams
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 15, 2021

By: /s/ John Leaman

John Leaman, M.D
Chief Financial Officer and Chief Business Officer
(Principal Financial and Accounting Officer)

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 6.3 AND 6.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

WARRANT TO PURCHASE COMMON STOCK

THIS WARRANT TO PURCHASE COMMON STOCK (as amended and in effect from time to time, this "**Warrant**") is issued as of the issue date set forth on Schedule I hereto (the "**Issue Date**") by the company set forth on Schedule I hereto (the "**Company**") to OXFORD FINANCE LLC, a Delaware limited liability company ("**Oxford**"), in connection with that certain Loan and Security Agreement dated as of July 2, 2021, among Oxford, as Lender and Collateral Agent, the Lenders from time to time party thereto, including Silicon Valley Bank, a California corporation, and the Company (as amended, modified, supplemented, or restated, and in effect from time to time, the "**Loan Agreement**"). The parties agree as follows:

SCHEDULE I. WARRANT PROVISIONS.

Warrant Section	**Warrant Provision**
Recitals – "Issue Date"	September 30, 2021
Recitals – "Company"	IMPEL NEUROPHARMA, INC., a Delaware corporation
1.1 – "Class"	Common Stock.
1.1 – "Exercise Price"	$12.95 per Share.
1.2 – "Shares"	11,583
6.1(a) – "Expiration Date"	September 30, 2031.

SECTION 1. RIGHT TO PURCHASE SHARES.

1.1 Grant of Right. For good and valuable consideration, the Company hereby grants to Oxford (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "**Holder**") the right, and Holder is entitled, to purchase from the Company up to the number of fully paid and non-assessable shares (as determined pursuant to Section 1.2 below) of the class set forth on Schedule I hereto (the "**Class**"), at a purchase price per Share set forth on Schedule I hereto (the "**Exercise Price**"), subject to the provisions and upon the terms and conditions set forth in this Warrant.

1.2 Number of Shares. This Warrant shall be exercisable for the number of shares of the Class as set forth on Schedule I hereto (as may be adjusted from time to time in accordance with the provisions of this Warrant, the "**Shares**").

SECTION 2. EXERCISE.

2.1 Method of Exercise. Holder may exercise this Warrant in whole or in part at any time and from time to time prior to the expiration or earlier termination of this Warrant, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 2.2 below,

a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Exercise Price for the Shares being purchased.

2.2 Cashless Exercise. On any exercise of this Warrant, in lieu of payment of the aggregate Exercise Price in the manner specified in Section 2.1 above, Holder may elect to surrender to the Company Shares having an aggregate value equal to the aggregate Exercise Price. If Holder makes such election, the Company shall issue to Holder such number of fully paid and non-assessable Shares determined by the following formula:

X = Y(A-B)/A

where:

X = the number of Shares to be issued to Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Exercise Price);

A = the fair market value (as determined pursuant to Section 2.3 below) of one Share; and B = the Exercise

Price.

2.3 Fair Market Value. If shares of the Company's common stock are then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "**Trading Market**") and the Class is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of the Company's common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If shares of the Company's common stock are not then traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

2.4 Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Sections 2.1 or 2.2 above, the Company shall deliver to Holder a certificate (or, in the case of uncertificated securities, provide notice of book entry) representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired (or surrendered in payment of the aggregate Exercise Price).

2.5 Replacement of Warrant. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

2.6 Treatment of Warrant Upon Acquisition of Company.

(a) Acquisition. "**Acquisition**" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company; (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization; or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power. For the avoidance of doubt, "Acquisition" shall not include any sale and issuance by the Company of shares of its capital stock or of securities or instruments exercisable for or convertible into, or otherwise representing the right to acquire, shares of its capital stock to one or more investors for cash in a transaction or series of related transactions the primary purpose of which is a bona fide equity financing of the Company.

(b) Treatment of Warrant in Cash/Public Acquisition. In the event of an Acquisition in which the consideration to be received by the holders of the outstanding shares of the Class (in their capacity as such) consists solely of cash, solely of Marketable Securities (as hereinafter defined) or a combination of cash and Marketable Securities (a "**Cash/Public Acquisition**"), and the fair market value of one Share as determined in accordance with Section 2.3 above would be greater than the Exercise Price in effect as of immediately prior to the closing of such Cash/Public Acquisition, and Holder has not previously exercised this Warrant in full, then, in lieu of Holder's exercise of the unexercised portion of this Warrant, this Warrant shall, as of immediately prior to such closing (but subject to the occurrence thereof) automatically cease to represent the right to purchase Shares and shall, from and after such closing, represent solely the right to receive the aggregate consideration that would have been payable in such Acquisition on and in respect of all Shares for which this Warrant was exercisable as of immediately prior to the closing thereof, net of the aggregate Exercise Price therefor, as if such Shares had been issued and outstanding to Holder as of immediately prior to such closing, as and when such consideration is paid to the holders of the outstanding shares of the Class. In the event of a Cash/Public Acquisition in which the fair market value of one Share as determined in accordance with Section 2.3 above would be equal to or less than the Exercise Price in effect as of immediately prior to the closing of such Cash/Public Acquisition, then this Warrant will automatically and without further action of any party terminate as of immediately prior to such closing.

(c) Treatment of Warrant in non-Cash/Public Acquisition. Upon the closing of any Acquisition other than a Cash/Public Acquisition, either (i) the acquiring, surviving or successor entity shall assume this Warrant and the Company's obligations hereunder, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, at an aggregate Exercise Price equal to the aggregate Exercise Price in effect as of immediately prior to such closing, all subject to further adjustment from time to time thereafter in accordance with the provisions of this Warrant or (ii) if the acquiring, surviving or successor entity shall not have assumed this Warrant, then the aggregate Exercise Price shall be reduced to the greater of (x) One Dollar ($1.00) or (y) the aggregate par value of the Shares and this Warrant shall be deemed to have been cashless exercised in full pursuant to Section 2.2 above as of immediately prior to the consummation of such Acquisition.

(d) Marketable Securities. "**Marketable Securities**" means securities meeting all of the following requirements (determined as of immediately prior to the closing of the Acquisition): (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition. Notwithstanding the foregoing provisions of this Section 2.6(d), securities held in escrow or subject to holdback to cover indemnification-related claims shall be deemed to be Marketable Securities if they would otherwise be Marketable Securities but for the fact that they are held in escrow or subject to holdback to cover indemnification-related claims.

SECTION 3. CERTAIN ADJUSTMENTS TO THE SHARES, CLASS AND EXERCISE PRICE.

3.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend or distribution on the outstanding shares of the Class payable in additional shares of the Class (including fractional shares) or other securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Class by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased, even if such number would include fractional shares, and the Exercise Price shall be proportionately decreased. If the outstanding shares of the Class are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Exercise Price shall be

proportionately increased and the number of Shares shall be proportionately decreased, even if such number would include fractional shares.

3.2 Reclassification, Exchange, Combination or Substitution. Upon any event whereby all of the outstanding shares of the Class are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, "Class" shall mean such securities and this Warrant will be exercisable for the number of such securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, at an aggregate Exercise Price equal to the aggregate Exercise Price in effect as of immediately prior to such event, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 3.2 shall similarly apply to successive reclassifications, exchanges, combinations, substitutions, replacements or other similar events.

3.3 Adjustment to Exercise Price on Cash Dividend. In the event that the Company at any time or from time to time prior to the exercise in full of this Warrant pays any cash dividend on the outstanding shares of the Class or makes any cash distribution on or in respect of all outstanding shares of the Class (other than a distribution of cash proceeds received by the Company in connection with an Acquisition described in Section 2.6(a)(i) above), then on and as of the date of each such dividend payment and/or distribution, the Exercise Price shall be reduced by an amount equal to the amount paid or distributed upon or in respect of each outstanding share of the Class; provided that in no event shall the Exercise Price be reduced below the then-par value, if any, of a share of the Class.

3.4 No Fractional Share. No fractional Share shall be issued upon exercise of this Warrant, and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of this Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash an amount equal to (a) such fractional interest, multiplied by (b)(i) the fair market value (as determined in accordance with Section 2.3 above) of a full Share, less (ii) the then-effective Exercise Price (the "**Fractional Share Value**"), unless Holder otherwise elects, in its sole discretion, to waive such payment. Notwithstanding any contrary provision herein, if this Warrant becomes exercisable for a fractional Share interest at any time or from time to time prior to the exercise in full of this Warrant, and the Company eliminates such fractional Share interest prior to any exercise of this Warrant, then the then-effective Exercise Price shall be reduced by an amount equal to the Fractional Share Value, unless Holder otherwise elects, in its sole discretion, to waive such reduction.

3.5 Certificate as to Adjustments. Within a reasonable time following each adjustment of the Exercise Price, Class and/or number of Shares pursuant to the terms of this Warrant, the Company, at its expense, shall deliver a certificate of its Chief Financial Officer or other authorized officer to Holder setting forth the adjustments to the Exercise Price, Class and/or number of Shares and the facts upon which such adjustments are based. The Company shall, at any time and from time to time within a reasonable time following Holder's written request and at the Company's expense, furnish Holder with a certificate of its Chief Financial Officer or other authorized officer setting forth the then-current Exercise Price, Class and number of Shares and the computations or other determinations thereof.

3.6 Adjustments for Diluting Issuances. Without duplication of any adjustment otherwise provided for in this Section 3, the number of shares of common stock issuable upon conversion of the Shares shall be subject to anti-dilution adjustment from time to time in the manner set forth in the Company's Certificate of Incorporation, as amended and in effect from time to time, as if the Shares were issued and outstanding on and as of the date of any such required adjustment.

SECTION 4. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

4.1 Representations and Warranties. The Company represents and warrants to, and agrees with, Holder as follows:

(a) All Shares which may be issued upon the exercise of this Warrant, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under the Company's Certificate of Incorporation or Bylaws, each as amended and in effect from time to time (the "**Charter Documents**"), any Stockholder Agreement (to the extent

Holder is then a party thereto or otherwise subject thereto in accordance with the provisions of Section 5.4 below) or applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of shares of the Class and other securities as will be sufficient to permit the exercise in full of this Warrant.

4.2 Notice of Certain Events. If the Company proposes at any time to:

(a) declare any dividend or distribution upon the outstanding shares of the Class, whether in cash, stock or other securities or property and whether or not a regular cash dividend;

(b) offer for subscription or sale pro rata to all holders of the outstanding shares of the Class any additional securities of the Company (other than pursuant to contractual pre-emptive or first refusal rights);

(c) effect any redemption, reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Class; or

(d) effect an Acquisition, or to liquidate, dissolve or wind up the Company.

then, in connection with each such event, the Company shall give Holder (pursuant to Section 6.5 below):

(1) in the case of the matters referred to in (a) and (b) above, at least seven (7) Business Days prior written notice of the earlier to occur of the effective date thereof or the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Class will be entitled thereto) or for determining rights to vote, if any; and

(2) in the case of the matters referred to in (c) and (d) above, at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event and such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such event giving rise to the notice).

2.1 Certain Company Information. The Company will provide such information requested by Holder from time to time, within a reasonable time following each such request, that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements. Prior to the IPO, such information may include, but shall not be limited to, the Company's then-current summary capitalization table, the price per share for which the Company most recently prior thereto sold or issued shares of its convertible preferred stock to investors for cash in a bona fide equity financing of the Company, and the Company's most recent 409A Valuation.

SECTION 5. REPRESENTATIONS AND COVENANTS OF HOLDER.

Holder represents and warrants to, and agrees with, the Company as follows:

5.1 Investment Representations.

(a) Purchase for Own Account. This Warrant and the Shares to be acquired upon exercise hereof are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

(b) Disclosure of Information. Holder is aware of the Company's business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions of and receive answers from the Company regarding the terms and

conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

(c) Investment Experience. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities for an indefinite period of time, and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

(d) Accredited Investor Status. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

(e) The Act. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act or registered or qualified under the securities laws of any state, and are issued in reliance upon specific exemptions therefrom, which exemptions depend upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that the Company is under no obligation to so register or qualify this Warrant, the Shares or such other securities. Holder understands that this Warrant and the Shares issued upon any exercise hereof are "restricted securities" under applicable federal and state securities laws and must be held indefinitely unless subsequently registered under the Act and registered or qualified under applicable state securities laws, or unless exemptions from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

5.2 No Stockholder Rights. Without limiting any provision of this Warrant, Holder agrees that as a Holder of this Warrant it will not have any rights (including, but not limited to, voting rights) as a stockholder of the Company with respect to the Shares issuable hereunder unless and until the exercise of this Warrant and then only with respect to the Shares issued on such exercise.

5.3 [Reserved].

5.4 Stockholder Agreements. Following any exercise of this Warrant and solely with respect to the Shares issued thereupon, if the Company so requests in writing, Holder shall become a party to the Company's then- effective right of first refusal and co-sale agreement, voting agreement and/or each other agreement entered into among the Company and holders of the outstanding shares of the Class, each as may be amended and in effect from time to time (collectively, the "**Stockholder Agreements**"), by execution and delivery to the Company of a counterpart signature page, joinder agreement, instrument of accession or similar instrument, provided that such Stockholder Agreement is by its terms in force and effect at the time of such exercise. If the foregoing condition is met, then effective upon such exercise, Holder shall automatically become bound by, and the Shares issued upon such exercise shall automatically become subject to, such Stockholder Agreement.

5.5 Confidential Information. Holder agrees to treat and hold all information provided by the Company pursuant to this Warrant in confidence in accordance with the provisions of Section 12.9 of the Loan Agreement (regardless of whether the Loan Agreement shall then be in effect).

SECTION 6. MISCELLANEOUS.

6.1 Term; Automatic Cashless Exercise Upon Expiration.

(a) Term. Subject to the provisions of Section 2.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the expiration date set forth on Schedule I hereto (the "**Expiration Date**") and shall be void thereafter; provided that if the Company does not deliver to Holder written confirmation of the fair market value of a Share pursuant to Section 6.1(b) below, then the Expiration

Date shall automatically be extended until the earlier to occur of (i) such date as the Company delivers such written confirmation and (ii) one (1) year after the Expiration Date.

(b) Automatic Cashless Exercise upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share as determined in accordance with Section 2.3 above is greater than the Exercise Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 2.2 above as to all Shares for which it shall not previously have been exercised, and the Company shall, within a reasonable time following Holder's written request, deliver a certificate (or, in the case of uncertificated securities, provide notice of book entry) representing the Shares issued to Holder upon such exercise. If shares of the Company's common stock are not then traded in a Trading Market, the Company shall deliver to Holder, prior to the Expiration Date, written confirmation of the fair market value of a Share (as determined pursuant to Section 2.3 above) to be used in determining whether this Warrant shall automatically exercise on the Expiration Date pursuant to this Section 6.1(b).

6.2 Legends. Each certificate or notice of book entry evidencing Shares shall be imprinted with a legend in substantially the following form (together with such additional legends as may be required by the Charter Documents or under any Stockholder Agreement (to the extent Holder is then a party thereto or otherwise subject thereto in accordance with the provisions of Section 5.4 above)):

THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE COMMON STOCK ISSUED BY THE ISSUER TO OXFORD FINANCE LLC DATED SEPTEMBER 30, 2021, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

6.3 Compliance with Securities Laws on Transfer. This Warrant and the Shares issued upon exercise hereof may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to any affiliate of Holder; provided that any such transferee is an "accredited investor" as defined in Regulation D promulgated under the Act. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of Rule 144 promulgated under the Act.

6.4 Transfer Procedure. After receipt by Oxford of the executed Warrant, Oxford may transfer all or part of this Warrant to one or more of Oxford's affiliates (each, an "**Oxford Affiliate**"), by execution of an Assignment substantially in the form of Appendix 2. Subject to the provisions of Section 6.3 and upon providing the Company with written notice, Oxford, any such Oxford Affiliate and any subsequent Holder, may transfer all or part of this Warrant or the Shares issuable upon exercise of this Warrant (or the Shares issuable directly or indirectly, upon conversion of the Shares, if any) to any other transferee, provided, however, in connection with any such transfer, the Oxford Affiliate(s) or any subsequent Holder will give the Company notice of the portion of the Warrant being transferred with the name, address and taxpayer identification number of the transferee and Holder will surrender this Warrant to the Company for reissuance to the transferee(s) (and Holder if applicable).

6.5 Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance

with the provisions of this Section 6.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

Oxford Finance LLC 115 South
Union Street Suite 300
Alexandria, VA 22314
Telephone: (703) 519-4900
Facsimile: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com

Notice to the Company shall be addressed as follows until Holder receives notice of a change in address: Impel NeuroPharma,

Inc.

201 Elliott Avenue West, Suite 260
Seattle, Washington 98119 Attn: Chief
Financial Officer

With a copy (which shall not constitute notice) to:

Fenwick & West LLP
1191 Second Avenue, 10th Floor Seattle,
WA 98101
Attn: Amanda Rose
Email: arose@fenwick.com

6.6 Amendment and Waiver. Notwithstanding any contrary provision herein or in the Loan Agreement, this Warrant may be amended and any provision hereof waived (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by Holder and any party against which enforcement of such amendment or waiver is sought.

6.7 Counterparts; Electronic Signatures; Status as Certificated Security. This Warrant may be executed by one or more of the parties hereto in any number of separate counterparts, all of which together shall constitute one and the same instrument. To the extent that this Warrant or any agreement subject to the terms hereof or any amendment hereto is delivered electronically, it shall be binding to the same extent as though it had been delivered on paper with an original ink signature, as provided under applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act. Physical possession of the original of this Warrant or any paper copy thereof shall confer no special status to the bearer thereof, other than to Holder.

6.8 Headings. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

6.9 Business Days. "**Business Day**" means any day that is not a Saturday, Sunday or a day on which banks in California are closed.

SECTION 7. GOVERNING LAW, VENUE AND JURY TRIAL WAIVER; JUDICIAL REFERENCE.

7.1 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

7.2 Jurisdiction and Venue. The Company and Holder each irrevocably and unconditionally submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Warrant shall be deemed to operate to preclude Holder from bringing suit or taking other legal action in any other jurisdiction to enforce a judgment or other court order in favor of Holder. The Company expressly, irrevocably and unconditionally submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and the Company hereby irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby irrevocably and unconditionally consents to the granting of such legal or equitable relief as is

deemed appropriate by such court. The Company hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to the Company in accordance with Section 6.5 of this Warrant and that service so made shall be deemed completed upon the earlier to occur of the Company's actual receipt thereof of three (3) days after deposit in the U.S. mails, proper postage prepaid.

7.3 Jury Trial Waiver. **TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE COMPANY AND HOLDER EACH WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS WARRANT, THE LOAN AGREEMENT OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR THE PARTIES' AGREEMENT TO THIS WARRANT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.**

7.4 Judicial Reference. **WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY**, if the waiver of the right to a trial by jury in Section 7.3 above is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure Sections 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure Section 644(a). Nothing in this Section 7.4 shall limit the right of any party at any time to exercise self-help remedies or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this Section 7.4.

7.5 Survival. This Section 7 shall survive the termination of this Warrant.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Wa1rnnt to Pw·chase Common Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

COMPANY:

IMPEL NEUROPHARMA, INC.

By:

Name:_____ Title: Chief Financial Officer

HOLDER:

OXFORD FINANCE LLC

By: ____ Name:

Title:

IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Common Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

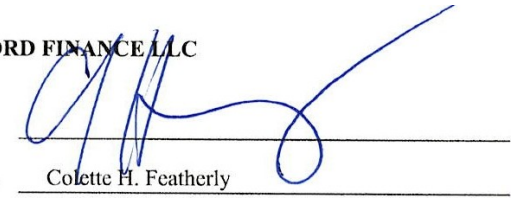
COMPANY:

IMPEL NEUROPHARMA, INC.

By:_____ Name:_____ Title: ____

HOLDER:

OXFORD FINANCE LLC

By: 

Name: Colette H. Featherly

Title: Senior Vice President

APPENDIX 1

Form of Notice of Exercise of Warrant

1. The undersigned Holder hereby exercises its right to purchase___shares of the Common Stock of IMPEL NEUROPHARMA, INC. (the "**Company**") in accordance with the attached Warrant To Purchase Stock, and tenders payment of the aggregate Exercise Price for such shares as follows:

[ ] Check in the amount of $____payable to order of the Company enclosed herewith

[ ] Wire transfer of immediately available funds to the Company's account

[ ] Cashless exercise pursuant to Section 2.2 of the Warrant, resulting in the issuance of ____shares of the Common Stock of the Company

[ ] Other [Describe]

2. Please issue a certificate or certificates (or evidence of book entry) representing the Shares in the name specified below:

Holder's Name

(Address)

3. By its execution below and for the benefit of the Company, Holder hereby makes each of the representations and warranties set forth in Section 5.1 of the Warrant To Purchase Stock as of the date hereof.

HOLDER:

By:_ Name:__ Title: ____

(Date): _

APPENDIX 2

Assignment

For value received, Oxford Finance LLC hereby sells, assigns and transfers unto Name:

[OXFORD TRANSFEREE]

Address: ____

Tax ID: ____]

that certain Warrant to Purchase Stock issued by IMPEL NEUROPHARMA, INC. (the "**Company**"), on September 30, 2021 (the "**Warrant**") together with all rights, title and interest therein.

OXFORD FINANCE LLC

By:_

Name:___

Title:____

Date:____

By its execution below, and for the benefit of the Company, [OXFORD TRANSFEREE] makes each of the representations and warranties set forth in Article 4 of the Warrant and agrees to all other provisions of the Warrant as of the date hereof.

[OXFORD TRANSFEREE]

By:_

Name:___

Title:____]

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 6.3 AND 6.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

WARRANT TO PURCHASE COMMON STOCK

THIS WARRANT TO PURCHASE COMMON STOCK (as amended and in effect from time to time, this "**Warrant**") is issued as of the issue date set forth on Schedule I hereto (the "**Issue Date**") by the company set forth on Schedule I hereto (the "**Company**") to SILICON VALLEY BANK, a California corporation ("**SVB**"), in connection with that certain Loan and Security Agreement dated as of July 2, 2021, among Oxford Finance LLC, as Lender and Collateral Agent, the Lenders from time to time party thereto, including SVB, and the Company (as amended, modified, supplemented, or restated, and in effect from time to time, the "**Loan Agreement**"), and shall be transferred to SVB FINANCIAL GROUP pursuant to Section 6.4 below. The parties agree as follows:

SCHEDULE I. WARRANT PROVISIONS.

Warrant Section	**Warrant Provision**
Recitals – "Issue Date"	September 30, 2021.
Recitals – "Company"	IMPEL NEUROPHARMA, INC., a Delaware corporation
1.1 – "Class"	Common Stock.
1.1 – "Exercise Price"	$12.95 per Share.
1.2 – "Shares"	11,583
6.1(a) – "Expiration Date"	September 30, 2031.

SECTION 1. RIGHT TO PURCHASE SHARES.

1.1 Grant of Right. For good and valuable consideration, the Company hereby grants to SVB (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "**Holder**") the right, and Holder is entitled, to purchase from the Company up to the number of fully paid and non-assessable shares (as determined pursuant to Section 1.2 below) of the class set forth on Schedule I hereto (the "**Class**"), at a purchase price per Share set forth on Schedule I hereto (the "**Exercise Price**"), subject to the provisions and upon the terms and conditions set forth in this Warrant.

1.2 Number of Shares. This Warrant shall be exercisable for the number of shares of the Class as set forth on Schedule I hereto (as may be adjusted from time to time in accordance with the provisions of this Warrant, the "**Shares**").

SECTION 2. EXERCISE.

2.1 Method of Exercise. Holder may exercise this Warrant in whole or in part at any time and from time to time prior to the expiration or earlier termination of this Warrant, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 2.2 below, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment

acceptable to the Company for the aggregate Exercise Price for the Shares being purchased. Notwithstanding any contrary provision herein, to the extent that the original of this Warrant is an electronic original, in no event shall an original ink-signed paper copy of this Warrant be required for any exercise of a Holder's rights hereunder, nor shall this Warrant or any physical copy hereof be required to be physically surrendered at the time of any exercise hereof.

2.2 Cashless Exercise. On any exercise of this Warrant, in lieu of payment of the aggregate Exercise Price in the manner specified in Section 2.1 above, Holder may elect to surrender to the Company Shares having an aggregate value equal to the aggregate Exercise Price. If Holder makes such election, the Company shall issue to Holder such number of fully paid and non-assessable Shares determined by the following formula:

X = Y(A-B)/A

where:

X = the number of Shares to be issued to Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Exercise Price);

A = the fair market value (as determined pursuant to Section 2.3 below) of one Share; and B = the Exercise Price.

2.3 Fair Market Value. If shares of the Company's common stock are then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "**Trading Market**") and the Class is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of the Company's common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If shares of the Company's common stock are not then traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

2.4 Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Sections 2.1 or 2.2 above, the Company shall deliver to Holder a certificate (or, in the case of uncertificated securities, provide notice of book entry) representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired (or surrendered in payment of the aggregate Exercise Price).

2.5 Replacement of Warrant.

(a) Paper Original Warrant. To the extent that the original of this Warrant is a paper original, on receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

(b) Electronic Original Warrant. To the extent that the original of this Warrant is an electronic original, if at any time this Warrant is rejected by any person (including, but not limited to, paying or escrow agents) or any such person fails to comply with the terms of this Warrant based on this Warrant being presented to such person as an electronic record or a printout hereof, or any signature hereto being in electronic form, the Company shall, promptly upon Holder's request and without indemnity, execute and deliver to Holder, in lieu of electronic original versions of this Warrant, a new warrant of like tenor and amount in paper form with original ink signatures.

2.6 Treatment of Warrant Upon Acquisition of Company.

(a) Acquisition. "**Acquisition**" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company; (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization; or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power. For the avoidance of doubt, "Acquisition" shall not include any sale and issuance by the Company of shares of its capital stock or of securities or instruments exercisable for or convertible into, or otherwise representing the right to acquire, shares of its capital stock to one or more investors for cash in a transaction or series of related transactions the primary purpose of which is a bona fide equity financing of the Company.

(b) Treatment of Warrant in Cash/Public Acquisition. In the event of an Acquisition in which the consideration to be received by the holders of the outstanding shares of the Class (in their capacity as such) consists solely of cash, solely of Marketable Securities (as hereinafter defined) or a combination of cash and Marketable Securities (a "**Cash/Public Acquisition**"), and the fair market value of one Share as determined in accordance with Section 2.3 above would be greater than the Exercise Price in effect as of immediately prior to the closing of such Cash/Public Acquisition, and Holder has not previously exercised this Warrant in full, then, in lieu of Holder's exercise of the unexercised portion of this Warrant, this Warrant shall, as of immediately prior to such closing (but subject to the occurrence thereof) automatically cease to represent the right to purchase Shares and shall, from and after such closing, represent solely the right to receive the aggregate consideration that would have been payable in such Acquisition on and in respect of all Shares for which this Warrant was exercisable as of immediately prior to the closing thereof, net of the aggregate Exercise Price therefor, as if such Shares had been issued and outstanding to Holder as of immediately prior to such closing, as and when such consideration is paid to the holders of the outstanding shares of the Class. In the event of a Cash/Public Acquisition in which the fair market value of one Share as determined in accordance with Section 2.3 above would be equal to or less than the Exercise Price in effect as of immediately prior to the closing of such Cash/Public Acquisition, then this Warrant will automatically and without further action of any party terminate as of immediately prior to such closing.

(c) Treatment of Warrant in non-Cash/Public Acquisition. Upon the closing of any Acquisition other than a Cash/Public Acquisition, either (i) the acquiring, surviving or successor entity shall assume this Warrant and the Company's obligations hereunder, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, at an aggregate Exercise Price equal to the aggregate Exercise Price in effect as of immediately prior to such closing, all subject to further adjustment from time to time thereafter in accordance with the provisions of this Warrant or (ii) if the acquiring, surviving or successor entity shall not have assumed this Warrant, then the aggregate Exercise Price shall be reduced to the greater of (x) One Dollar ($1.00) or (y) the aggregate par value of the Shares and this Warrant shall be deemed to have been cashless exercised in full pursuant to Section 2.2 above as of immediately prior to the consummation of such Acquisition.

(d) Marketable Securities. "**Marketable Securities**" means securities meeting all of the following requirements (determined as of immediately prior to the closing of the Acquisition): (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition. Notwithstanding the foregoing provisions of this Section 2.6(d), securities held in escrow or subject to holdback to cover indemnification-related claims shall be

deemed to be Marketable Securities if they would otherwise be Marketable Securities but for the fact that they are held in escrow or subject to holdback to cover indemnification-related claims.

SECTION 3. CERTAIN ADJUSTMENTS TO THE SHARES, CLASS AND EXERCISE PRICE.

3.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend or distribution on the outstanding shares of the Class payable in additional shares of the Class (including fractional shares) or other securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Class by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased, even if such number would include fractional shares, and the Exercise Price shall be proportionately decreased. If the outstanding shares of the Class are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Exercise Price shall be proportionately increased and the number of Shares shall be proportionately decreased, even if such number would include fractional shares.

3.2 Reclassification, Exchange, Combination or Substitution. Upon any event whereby all of the outstanding shares of the Class are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, "Class" shall mean such securities and this Warrant will be exercisable for the number of such securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, at an aggregate Exercise Price equal to the aggregate Exercise Price in effect as of immediately prior to such event, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 3.2 shall similarly apply to successive reclassifications, exchanges, combinations, substitutions, replacements or other similar events.

3.3 Adjustment to Exercise Price on Cash Dividend. In the event that the Company at any time or from time to time prior to the exercise in full of this Warrant pays any cash dividend on the outstanding shares of the Class or makes any cash distribution on or in respect of all outstanding shares of the Class (other than a distribution of cash proceeds received by the Company in connection with an Acquisition described in Section 2.6(a)(i) above), then on and as of the date of each such dividend payment and/or distribution, the Exercise Price shall be reduced by an amount equal to the amount paid or distributed upon or in respect of each outstanding share of the Class; provided that in no event shall the Exercise Price be reduced below the then-par value, if any, of a share of the Class.

3.4 No Fractional Share. No fractional Share shall be issued upon exercise of this Warrant, and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of this Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash an amount equal to (a) such fractional interest, multiplied by (b)(i) the fair market value (as determined in accordance with Section 2.3 above) of a full Share, less (ii) the then-effective Exercise Price (the "**Fractional Share Value**"), unless Holder otherwise elects, in its sole discretion, to waive such payment. Notwithstanding any contrary provision herein, if this Warrant becomes exercisable for a fractional Share interest at any time or from time to time prior to the exercise in full of this Warrant, and the Company eliminates such fractional Share interest prior to any exercise of this Warrant, then the then-effective Exercise Price shall be reduced by an amount equal to the Fractional Share Value, unless Holder otherwise elects, in its sole discretion, to waive such reduction.

3.5 Certificate as to Adjustments. Within a reasonable time following each adjustment of the Exercise Price, Class and/or number of Shares pursuant to the terms of this Warrant, the Company, at its expense, shall deliver a certificate of its Chief Financial Officer or other authorized officer to Holder setting forth the adjustments to the Exercise Price, Class and/or number of Shares and the facts upon which such adjustments are based. The Company shall, at any time and from time to time within a reasonable time following Holder's written request and at the Company's expense, furnish Holder with a certificate of its Chief Financial Officer or other authorized officer setting forth the then-current Exercise Price, Class and number of Shares and the computations or other determinations thereof.

3.6 Adjustments for Diluting Issuances. Without duplication of any adjustment otherwise provided for in this Section 3, the number of shares of common stock issuable upon conversion of the Shares shall be subject to anti-dilution adjustment from time to time in the manner set forth in the Company's Certificate of Incorporation, as amended and in effect from time to time, as if the Shares were issued and outstanding on and as of the date of any such required adjustment.

SECTION 4. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

4.1 Representations and Warranties. The Company represents and warrants to, and agrees with, Holder as follows:

(a) All Shares which may be issued upon the exercise of this Warrant, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under the Company's Certificate of Incorporation or Bylaws, each as amended and in effect from time to time (the "**Charter Documents**"), any Stockholder Agreement (to the extent Holder is then a party thereto or otherwise subject thereto in accordance with the provisions of Section 5.4 below) or applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of shares of the Class and other securities as will be sufficient to permit the exercise in full of this Warrant.

4.2 Notice of Certain Events. If the Company proposes at any time to:

(a) declare any dividend or distribution upon the outstanding shares of the Class, whether in cash, stock or other securities or property and whether or not a regular cash dividend;

(b) offer for subscription or sale pro rata to all holders of the outstanding shares of the Class any additional securities of the Company (other than pursuant to contractual pre-emptive or first refusal rights);

(c) effect any redemption, reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Class; or

(d) effect an Acquisition, or to liquidate, dissolve or wind up the Company.

then, in connection with each such event, the Company shall give Holder (pursuant to Section 6.5 below):

(1) in the case of the matters referred to in (a) and (b) above, at least seven (7) Business Days prior written notice of the earlier to occur of the effective date thereof or the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Class will be entitled thereto) or for determining rights to vote, if any; and

(2) in the case of the matters referred to in (c) and (d) above, at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event and such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such event giving rise to the notice).

4.3 Certain Company Information. The Company will provide such information requested by Holder from time to time, within a reasonable time following each such request, that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements. Prior to the IPO, such information may include, but shall not be limited to, the Company's then-current summary capitalization table, the price per share for which the Company most recently prior thereto sold or issued shares of its convertible preferred stock to investors for cash in a bona fide equity financing of the Company, and the Company's most recent 409A Valuation.

SECTION 5. REPRESENTATIONS AND COVENANTS OF HOLDER.

Holder represents and warrants to, and agrees with, the Company as follows:

5.1 Investment Representations.

(a) Purchase for Own Account. Except for the one-time transfer of this Warrant from Silicon Valley Bank to its parent SVB Financial Group described in Section 6.4 below, this Warrant and the Shares to be acquired upon exercise hereof are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

(b) Disclosure of Information. Holder is aware of the Company's business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions of and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

(c) Investment Experience. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities for an indefinite period of time, and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

(d) Accredited Investor Status. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

(e) The Act. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act or registered or qualified under the securities laws of any state, and are issued in reliance upon specific exemptions therefrom, which exemptions depend upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that the Company is under no obligation to so register or qualify this Warrant, the Shares or such other securities. Holder understands that this Warrant and the Shares issued upon any exercise hereof are "restricted securities" under applicable federal and state securities laws and must be held indefinitely unless subsequently registered under the Act and registered or qualified under applicable state securities laws, or unless exemptions from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

5.2 No Stockholder Rights. Without limiting any provision of this Warrant, Holder agrees that as a Holder of this Warrant it will not have any rights (including, but not limited to, voting rights) as a stockholder of the Company with respect to the Shares issuable hereunder unless and until the exercise of this Warrant and then only with respect to the Shares issued on such exercise.

5.3 [Reserved].

5.4 Stockholder Agreements. Following any exercise of this Warrant and solely with respect to the Shares issued thereupon, if the Company so requests in writing, Holder shall become a party to the Company's then-effective right of first refusal and co-sale agreement, voting agreement and/or each other agreement entered into among the Company and holders of the outstanding shares of the Class, each as may be amended and in effect from time to time (collectively, the "**Stockholder Agreements**"), by execution and delivery to the Company of a counterpart signature page, joinder agreement, instrument of accession or similar instrument, provided that such Stockholder

Agreement is by its terms in force and effect at the time of such exercise. If the foregoing condition is met, then effective upon such exercise, Holder shall automatically become bound by, and the Shares issued upon such exercise shall automatically become subject to, such Stockholder Agreement.

5.5 Confidential Information. Holder agrees to treat and hold all information provided by the Company pursuant to this Warrant in confidence in accordance with the provisions of Section 12.9 of the Loan Agreement (regardless of whether the Loan Agreement shall then be in effect).

SECTION 6. MISCELLANEOUS.

6.1 Term; Automatic Cashless Exercise Upon Expiration.

(a) Term. Subject to the provisions of Section 2.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the expiration date set forth on Schedule I hereto (the "**Expiration Date**") and shall be void thereafter; provided that if the Company does not deliver to Holder written confirmation of the fair market value of a Share pursuant to Section 6.1(b) below, then the Expiration Date shall automatically be extended until the earlier to occur of (i) such date as the Company delivers such written confirmation and (ii) one (1) year after the Expiration Date.

(b) Automatic Cashless Exercise upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share as determined in accordance with Section 2.3 above is greater than the Exercise Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 2.2 above as to all Shares for which it shall not previously have been exercised, and the Company shall, within a reasonable time following Holder's written request, deliver a certificate (or, in the case of uncertificated securities, provide notice of book entry) representing the Shares issued to Holder upon such exercise. If shares of the Company's common stock are not then traded in a Trading Market, the Company shall deliver to Holder, prior to the Expiration Date, written confirmation of the fair market value of a Share (as determined pursuant to Section 2.3 above) to be used in determining whether this Warrant shall automatically exercise on the Expiration Date pursuant to this Section 6.1(b).

6.2 Legends. Each certificate or notice of book entry evidencing Shares shall be imprinted with a legend in substantially the following form (together with such additional legends as may be required by the Charter Documents or under any Stockholder Agreement (to the extent Holder is then a party thereto or otherwise subject thereto in accordance with the provisions of Section 5.4 above)):

> THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE COMMON STOCK ISSUED BY THE ISSUER TO SILICON VALLEY BANK DATED SEPTEMBER 30, 2021 MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

6.3 Compliance with Securities Laws on Transfer. This Warrant and the Shares issued upon exercise hereof may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to SVB Financial Group (Silicon Valley Bank's parent company) or any other affiliate of Holder; provided that any such transferee is an "accredited investor" as defined in Regulation D promulgated under the Act.

6.4 Transfer Procedure. After receipt by Silicon Valley Bank of the executed Warrant, Silicon Valley Bank will transfer, for value received, all of its rights, title and interest in and to this Warrant to its parent company, SVB Financial Group, without any separate assignment agreement. By its acceptance of this Warrant, SVB Financial Group, on and as of the date of such assignment, hereby makes to the Company each of the representations and warranties set forth in Section 5.1 hereof and agrees to be bound by all of the terms and conditions of this Warrant as if it were the original Holder hereof. Subject to the provisions of Section 6.3 and upon providing the Company with written notice, SVB Financial Group and any subsequent Holder may transfer all or part of this Warrant or the Shares issued upon exercise of this Warrant to any transferee; provided that in connection with any such transfer, SVB Financial Group or any subsequent Holder will give the Company notice of the portion of the Warrant and/or Shares being transferred with the name, address and taxpayer identification number of the transferee, and Holder will surrender this Warrant, or the certificates or other evidence of such Shares or other securities, to the Company for reissuance to the transferee(s) (and to Holder if applicable); and provided further, that any subsequent transferee other than SVB Financial Group shall make substantially the representations set forth in Section 5.1 above and shall agree in writing with the Company to be bound by all of the terms and conditions of this Warrant; and provided further, that the transfer of any Shares issued on exercise hereof shall be subject to the provisions of the Stockholder Agreements to the extent Holder is then a party thereto or otherwise subject thereto in accordance with the provisions of Section 5.4 above.

6.5 Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 6.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

SVB Financial
Group Attn:
Warrants
80 East Rio Salado Parkway, Suite 600
Tempe, AZ 85281
Telephone: (480) 557-4900
Email: SVBFGWarrants@svb.com

All notices to the Company shall be addressed as follows until Holder receives notice of a change in address: Impel

NeuroPharma, Inc.

201 Elliott Avenue West, Suite 260
Seattle, Washington 98119
Attn: Chief Financial Officer

With a copy (which shall not constitute notice) to:

Fenwick & West LLP
1191 Second Avenue, 10th Floor
Seattle, WA 98101
Attn: Amanda Rose
Email: arose@fenwick.com

6.6 Amendment and Waiver. Notwithstanding any contrary provision herein or in the Loan Agreement, this Warrant may be amended and any provision hereof waived (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by Holder and any party against which enforcement of such amendment or waiver is sought.

6.7 Counterparts; Electronic Signatures; Status as Certificated Security. This Warrant may be executed by one or more of the parties hereto in any number of separate counterparts, all of which together shall constitute one and the same instrument. The Company, Holder and any other party hereto may execute this Warrant by electronic

means and each party hereto recognizes and accepts the use of electronic signatures and the keeping of records in electronic form by any other party hereto in connection with the execution and storage hereof. To the extent that this Warrant or any agreement subject to the terms hereof or any amendment hereto is executed, recorded or delivered electronically, it shall be binding to the same extent as though it had been executed on paper with an original ink signature, as provided under applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act. The fact that this Warrant is executed, signed, stored or delivered electronically shall not prevent the transfer by any Holder of this Warrant pursuant to Section 6.4 or the enforcement of the terms hereof. To the extent that the original of this Warrant is an electronic original, this Warrant, and any copies hereof, shall NOT be deemed to be a "certificated security" within the meaning of Section 8102(a)(4) of the California Commercial Code. Physical possession of the original of this Warrant or any paper copy thereof shall confer no special status to the bearer thereof.

6.8 Headings. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

6.9 Business Days. "**Business Day**" means any day that is not a Saturday, Sunday or a day on which banks in California are closed.

SECTION 7. GOVERNING LAW, VENUE AND JURY TRIAL WAIVER; JUDICIAL REFERENCE.

7.1 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

7.2 Jurisdiction and Venue. The Company and Holder each irrevocably and unconditionally submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Warrant shall be deemed to operate to preclude Holder from bringing suit or taking other legal action in any other jurisdiction to enforce a judgment or other court order in favor of Holder. The Company expressly, irrevocably and unconditionally submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and the Company hereby irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby irrevocably and unconditionally consents to the granting of such legal or equitable relief as is deemed appropriate by such court. The Company hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to the Company in accordance with Section 6.5 of this Warrant and that service so made shall be deemed completed upon the earlier to occur of the Company's actual receipt thereof of three (3) days after deposit in the U.S. mails, proper postage prepaid.

7.3 Jury Trial Waiver. **TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE COMPANY AND HOLDER EACH WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS WARRANT, THE LOAN AGREEMENT OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR THE PARTIES' AGREEMENT TO THIS WARRANT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.**

7.4 Judicial Reference. **WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY**, if the waiver of the right to a trial by jury in Section 7.3 above is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure Sections 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and

permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure Section 644(a). Nothing in this Section 7.4 shall limit the right of any party at any time to exercise self-help remedies or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this Section 7.4.

7.5 Survival. This Section 7 shall survive the termination of this Warrant.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Common Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

COMPANY:

IMPEL NEU

By:

Name: John Leaman

Title: ChiefFinancial Officer

HOLDER:

SILICON VALLEY BANK

By:_ Name:__ Title:

IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Common Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

COMPANY:

IMPEL NEUROPHARMA, INC.

By: ____

Name: _____

Title: ____

HOLDER:

SILICON VALLEY BANK

By: ____

Name: Title:

Max Eberhart

Vice President

APPENDIX 1

Form of Notice of Exercise of Warrant

1. The undersigned Holder hereby exercises its right to purchase shares of the Common Stock of IMPEL NEUROPHARMA, INC. (the "**Company**") in accordance with the attached Warrant To Purchase Stock, and tenders payment of the aggregate Exercise Price for such shares as follows:

[ ] Check in the amount of $ payable to order of the Company enclosed herewith

[ ] Wire transfer of immediately available funds to the Company's account

[ ] Cashless exercise pursuant to Section 2.2 of the Warrant, resulting in the issuance of shares of the Common Stock of the Company

[ ] Other [Describe]

2. Please issue a certificate or certificates (or evidence of book entry) representing the Shares in the name specified below:

Holder's
Name

(Address)

3. By its execution below and for the benefit of the Company, Holder hereby makes each of the representations and warranties set forth in Section 5.1 of the Warrant To Purchase Stock as of the date hereof.

HOLDER:

By: Name: Title:

(Date):

119685516v2 030690.000085

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adrian Adams, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Impel NeuroPharma, 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 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)) 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) 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

   c) disclosed in this report any change in the 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.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

By: /s/ Adrian Adams
Adrian Adams
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Leaman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Impel NeuroPharma, 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 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)) 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. 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

   c. disclosed in this report any change in the 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.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

By: /s/ John Leaman

John Leaman
Chief Financial Officer and Chief Business Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Adrian Adams, Chief Executive Officer of Impel NeuroPharma, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition, and results of operations of the Company.

Date: November 15, 2021

By: /s/ Adrian Adams
Adrian Adams
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, John Leaman, Chief Financial Officer of Impel NeuroPharma, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition, and results of operations of the Company.

Date: November 15, 2021

By: /s/ John Leaman
John Leaman
Chief Financial Officer and Chief Business Officer
(Principal Accounting and Financial Officer)