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 March 31, 2023

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 PHARMACEUTICALS 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 LLC

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 May 8, 2023 was 23,749,005.

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 execute our commercialization strategy for Trudhesa;
- our expectations regarding our plans to pursue a new strategic reprioritization, halt research and development on certain product candidates, and the associated cost savings;
- the size and growth potential of the market for Trudhesa and the markets for any future product candidates, if approved for commercial use, and our ability to serve those markets;
- our ability to obtain and maintain regulatory approval of any future 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 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 product candidates, including plans for future development of our POD devices and proprietary POD technology, 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 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 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;
- general macroeconomic conditions, and any related impacts from rising inflation, interest rates or geopolitical conflict;
- 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.

Table of Contents

		Page
	PART I—FINANCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements (unaudited)	4
	Condensed Consolidated Balance Sheets	4
	Condensed Consolidated Statements of Operations and Comprehensive Loss	5
	Condensed Consolidated Statements of Changes in Stockholders' (Deficit) Equity	6
	Condensed Consolidated Statements of Cash Flows	7
	Notes to the Condensed Consolidated Financial Statements	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	26
Item 4.	Controls and Procedures	26
	PART II—OTHER INFORMATION	
Item 1.	Legal Proceedings	27
Item 1A.	Risk Factors	27
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	63
Item 3.	Defaults Upon Senior Securities	63
Item 4.	Mine Safety Disclosures	63
Item 5.	Other Information	63
Item 6.	Exhibits	64
EXHIBIT INDEX		64
SIGNATURES		65

In this Quarterly Report on Form 10-Q, "we," "our," "us," "Impel" and the "Company" refer to Impel Pharmaceuticals Inc. and its consolidated subsidiary. Impel, Impel Pharmaceuticals Inc., the Impel logo and other trade names, trademarks or service marks of Impel are the property of Impel Pharmaceuticals 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 PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheet
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 35,465	$ 60,654
Trade receivables, net	6,280	7,444
Inventory	8,014	8,427
Prepaid expenses and other current assets	2,125	3,284
Total current assets	51,884	79,809
Property and equipment, net	4,081	3,863
Operating lease right-of-use assets	4,833	3,132
Other assets	3,931	1,746
Total assets	$ 64,729	$ 88,550
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 6,133	$ 6,092
Accrued and other liabilities	11,723	12,503
Current portion of deferred royalty obligation	2,690	2,027
Current portion of operating lease liability	1,736	1,541
Total current liabilities	22,282	22,163
Operating lease liability, net of current portion	3,074	1,573
Deferred royalty obligation, net of current portion	64,183	60,899
Long-term debt	48,095	48,072
Total liabilities	137,634	132,707
Commitments and contingencies (Note 6)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized: none issued	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 23,746,257 and 23,739,313 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	24	24
Additional paid-in capital	278,248	276,929
Accumulated deficit	(351,177)	(321,110)
Total stockholders' (deficit) equity	(72,905)	(44,157)
Total liabilities and stockholders' (deficit) equity	$ 64,729	$ 88,550

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

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

	Three Months Ended March 31,	
	2023	2022
Product revenue, net	$ 4,372	$ 1,759
Cost of goods sold	2,285	1,033
Gross profit	2,087	726
Operating expenses:		
Research and development	3,003	3,650
Selling, general and administrative	22,037	19,799
Restructuring	1,483	—
Total operating expenses	26,523	23,449
Loss from operations	(24,436)	(22,723)
Other income (expense), net :		
Interest income (expense), net	(2,933)	(4,427)
Other income (expense), net	(2,698)	180
Total other income (expense), net	(5,631)	(4,247)
Loss before income taxes	(30,067)	(26,970)
Provision (benefit) for income taxes	—	—
Net loss and comprehensive loss	$ (30,067)	$ (26,970)
Net loss per share - basic and diluted	$ (1.27)	$ (1.17)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	23,745,871	23,143,773

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

IMPEL PHARMACEUTICALS INC.
Condensed Consolidated Statement of Changes in Stockholders' (Deficit) Equity
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount			
Balance — December 31, 2022	23,739,313	$ 24	$ 276,929	$ (321,110)	$ (44,157)
Stock-based compensation expense	—	—	1,319	—	1,319
Release of restricted stock units	6,944	—	—	—	—
Net loss and comprehensive loss	—	—	—	(30,067)	(30,067)
Balance — March 31, 2023	23,746,257	$ 24	$ 278,248	$ (351,177)	$ (72,905)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance — December 31, 2021	23,123,062	$ 23	$ 267,283	$ (214,798)	$ 52,508
Stock-based compensation expense	—	—	1,795	—	1,795
Issuance of common stock upon the exercise of stock options	50,235	—	149	—	149
Net loss and comprehensive loss	—	—	—	(26,970)	(26,970)
Balance — March 31, 2022	23,173,297	$ 23	$ 269,227	$ (241,768)	$ 27,482

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

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

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (30,067)	$ (26,970)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,319	1,795
Depreciation and amortization	272	310
Non-cash lease expense	392	232
Non-cash interest expense and amortization of debt discount and issuance costs	1,100	484
Loss on early extinguishment of debt	—	3,251
Change in fair value of derivatives	2,870	—
Change in fair value of warrant liabilities	(182)	(187)
Write-down of inventory to net realizable value	829	—
Long-lived asset impairment	417	—
Changes in operating assets and liabilities:		
Accounts receivable	1,164	(2,534)
Inventory	(1,117)	(2,672)
Prepaid expenses and other current assets	1,158	(777)
Other assets	(19)	—
Accounts payable	41	2,628
Accrued liabilities	(1,923)	448
Operating lease	(397)	(219)
Net cash used in operating activities	$ (24,143)	$ (24,211)
Cash flows from investing activities:		
Purchases of property and equipment	(1,046)	(8)
Net cash used in investing activities	$ (1,046)	$ (8)
Cash flows from financing activities:		
Proceeds from deferred royalty obligation, net of issuance costs	—	49,774
Proceeds from issuance of long-term debt, net of issuance costs	—	48,774
Payments on long-term debt, including final payment	—	(32,853)
Proceeds from issuance of common stock upon exercise of stock options	—	149
Net cash provided by financing activities	$ —	$ 65,844
Net (decrease) increase in cash and cash equivalents	(25,189)	41,625
Cash — Beginning of period	60,654	88,212
Cash — End of period	$ 35,465	$ 129,837
Supplemental disclosures of cash flow information:		
Right-of-use asset obtained in exchange for new operating lease liability	$ 2,093	$ 2,812
Accrued inventory purchases	1,465	—
Recognition of derivative liabilities	—	1,905
Purchase of property and equipment included in accounts payable and accrued liabilities	166	—
Debt issuance costs included in accounts payable and accrued liabilities	—	2,569

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

1. Organization and Description of Business

Impel Pharmaceuticals Inc. (“the Company”, "we", and "our"), is a commercial-stage biopharmaceutical 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") in September of 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. In April of 2022, the Company changed its name from Impel NeuroPharma, Inc. to Impel Pharmaceuticals Inc.

Liquidity and Capital Resources

From the Company’s inception through March 31, 2023, it raised an aggregate of $397.8 million in proceeds from the issuance of its common stock, proceeds pursuant to the Revenue Interest Financing Agreement (deferred royalty obligation), sale and issuance of redeemable convertible preferred stock, convertible notes, debt and warrants. The Company had a cash and cash equivalents balance of $35.5 million as of March 31, 2023. The Company currently has an effective 2022 Shelf Registration Statement on file with the Securities and Exchange Commission ("SEC"). The 2022 Shelf Registration Statement permits the offering, issuance and sale by the Company of up to an aggregate offering price of $200.0 million of common stock, preferred stock, debt securities, warrants, subscription rights and/or units in one or more offerings and in any combination.

Further, the Senior Credit Agreement with Oaktree Fund Administration, LLC as administrative agent, and the lenders party thereto, or collectively Oaktree, as further described in Note 8, requires maintaining a minimum of $12.5 million in unrestricted cash and cash equivalents on hand to avoid an event of default under the Senior Credit Agreement. Based on our cash and cash equivalents on hand of approximately $35.5 million at March 31, 2023, the Company estimates that it will need to raise additional capital to avoid defaulting under its $12.5 million minimum cash liquidity covenant. Among other loan covenant requirements, the Senior Credit Agreement also requires the Company to provide an audit opinion of its annual financial statements not subject to any "going concern" or like qualification or exception or explanatory paragraph of going concern footnote, however, any such audit report shall not be considered qualified due to the inclusion of an explanatory paragraph in the audit opinion based on the impending maturity date of any indebtedness within twelve months from the date of issuance of these financial statements, the prospective breach of any financial covenant hereunder or liquidity issues due to ordinary course liabilities. If the Company defaults under its Senior Credit Agreement, the lenders may accelerate all of the Company's repayment obligations and take control of its pledged assets. The lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect as defined under the Senior Credit Agreement and the Revenue Interest Financing Agreement, thereby requiring the Company to repay the loans immediately or to attempt to reverse the lenders’ declaration through negotiation or litigation. On March 22, 2023, the Company entered into the Oaktree Letter Agreement in connection with its Senior Credit Agreement, to obtain a waiver from Oaktree of any default or event of default arising from the going concern explanatory paragraph included in the report of its Independent Registered Public Accounting Firm on its audited consolidated financial statements for the year ended December 31, 2022.

The Company plans to address this condition through additional equity financings, or through other capital sources, including collaborations with other companies or other strategic transactions. To the extent that the Company may need to raise additional funds by issuing equity securities, its stockholders may experience significant dilution. If sufficient funds on acceptable terms are not available when needed, the Company could be required to reduce operating expenses and reduce the scope of its commercialization plans for Trudhesa. 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 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, and rules and regulations of the SEC for interim financial reporting. The condensed consolidated financial statements include the operations of Impel Pharmaceuticals Inc., and its wholly owned Australian subsidiary. All intercompany balances and transactions have been eliminated upon consolidation.

The condensed consolidated balance sheet as of March 31, 2023, the condensed consolidated statements of operations and comprehensive loss, changes in stockholders' (deficit) equity and cash flows for the three months ended March 31, 2023 and 2022 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 March 31, 2023 and its results of operations and cash flows for the three months ended March 31, 2023 and 2022. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the three month period is also unaudited. The results of operations for the three months ended March 31, 2023, are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2022 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 financial statements as of and for the year ended December 31, 2022 included in its Annual Report on Form 10-K filed with the SEC on March 27, 2023.

Our significant accounting policies are described in Note 2 of the notes to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022. Updates to our accounting policies, including impacts from the adoption of new accounting standards, are discussed below in this Note 2.

Use of Estimates

The preparation of 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 derivative liabilities, stock-based compensation expense, deferred royalty obligation, lease accounting, income taxes, and additional charges as a result of, or that are associated with, any restructuring initiative as well as impairment and related charges. 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 Chairman and Chief Executive Officer. The Chairman and 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.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and accounts receivables. 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.

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 $2.8 million and $2.1 million for the three months ended March 31, 2023 and 2022, respectively

Recently Adopted Accounting Pronouncements

In June 2016 the FASB issued Accounting Standard Update ("ASU") 2016-13, Measurement of Credit Losses on Financial Instruments (Topic 326). This introduces new methodology for recognition of credit losses - the current expected credit loss ("CECL")

method. The CECL method requires the recognition of all losses expected over the life of a financial instrument upon origination or purchase of the instrument, unless the company elects to recognize such instruments at fair value with changes in profit and loss. The Company adopted this guidance as of January 1, 2023. The adoption did not have a material impact to the Company or its disclosures.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("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. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (1) no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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):

	March 31, 2023			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$ 79	$ 79
Derivative liability - Deferred royalty obligation	—	—	14,000	14,000
Derivative liability - Oaktree term loan	—	—	430	430
Total financial liabilities	$ —	$ —	$ 14,509	$ 14,509

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$ 261	$ 261
Derivative liability - Deferred royalty obligation	—	—	11,000	11,000
Derivative liability - Oaktree term loan	—	—	560	560
Total financial liabilities	$ —	$ —	$ 11,821	$ 11,821

The following table summarizes the change in the fair value of the common stock warrant liabilities for the three months ended March 31, 2023 (in thousands):

Beginning balance as of December 31, 2022	$ 261
Changes in fair value	(182)
Ending balance as of March 31, 2023	$ 79

The following table summarizes the change in the estimated fair value of the Company's derivative liabilities for the three months ended March 31, 2023 (in thousands):

Beginning balance as of December 31, 2022	$ 11,560
Change in fair value of derivatives - Deferred royalty obligation	3,000
Change in fair value of derivatives - Oaktree term loan	(130)
Ending balance as of March 31, 2023	$ 14,430

Fair values of the Company's common stock warrants and the derivative liabilities are based on significant inputs not observed in the market, and thus represent a Level 3 measurement.

The Senior Credit Agreement with Oaktree contains embedded derivatives requiring bifurcation as a derivative instrument. The derivative liability related to the Oaktree term loan is netted with the term loan in the consolidated financial statements (see Note 6 for additional details). The embedded derivative liability is subject to remeasurement at the end of each reporting period, with changes in fair value recognized as a component of other expense, net. The fair value of the embedded derivative liabilities associated with the term loan was estimated using a probability weighted discounted cash flow model to measure the fair value. This involves significant Level

3 inputs and assumptions including an (i) estimated probability and timing of a change in control and event of default, and (ii) our risk-adjusted discount rate.

The embedded derivative liability associated with our deferred royalty obligation (see Note 8) is measured at fair value using an option pricing Monte Carlo simulation model and is netted with the deferred royalty obligation in the consolidated financial statements. The embedded derivative liability is subject to remeasurement at the end of each reporting period, with changes in fair value recognized as a component of other expense, net. The assumptions used in the option pricing Monte Carlo simulation model include:(i) the probability-weighted net sales of Trudhesa; (ii) our risk-adjusted discount rate; (iii) our cost of debt; and (iv) the probability of a change in control and event of default occurring during the term of the instrument. The effect of an increase or decrease of 5% of the probability of (i) a change in control, (ii) event of default and (iii) forecast net sales of Trudhesa, would result in a gain of $1.9 million or a loss of $1.8 million, respectively. The increase in the fair value of the embedded derivative liability at March 31, 2023 was based on changes in the expectations of timing and probability of occurrence of a change in control and event of default.

Pursuant to the July 2021 loan and security agreement with Oxford Finance LLC and Silicon Valley Bank (the "Loan Agreement"), the Company issued common stock warrants (see Note 8). 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 income (expense), net in the consolidated statement of operations and other comprehensive loss. The Company determined the fair value of the common stock warrants using the Black-Scholes-Merton option pricing model based on significant unobservable inputs. The significant unobservable inputs used in the fair value measurement of the warrant liabilities is the volatility rate which is based on the historical volatility of a set of peer companies, that are publicly traded.

4. Corporate Restructuring

On February 22, 2023, the Company announced a strategic update and corporate restructuring (the "Restructuring") to reprioritize spend to capitalize on the continued positive momentum in payor and prescriber uptake of Trudhesa and halt research and development efforts on product candidates including INP105 to address acute agitation and aggression in autism spectrum disorder. As part of the Restructuring, the Company reduced headcount by 16% through a reduction in its workforce. The reduction in workforce was completed by March 31, 2023.

The Company incurred the following Restructuring charges consisting of winding down costs, exit and other related costs, impairments and write-offs of long-lived assets, and severance and employee-related costs (in thousands):

	Three Months Ended March 31, 2023
Severance and employee-related costs	$ 1,007
Long-lived asset impairments and write-offs	417
Supplemental one-time termination charges	59
Total	$ 1,483

The Company estimated that it will incur total cash expenses of approximately $1.0 million related to the Restructuring of which $0.5 million was paid in the first quarter of 2023. The cash payments were primarily comprised of severance and other related costs.

The Company also completed an evaluation of the impact of the Restructuring on the carrying value of its long-lived assets, such as property and equipment. This process includes evaluating the estimated remaining lives, significant changes in the use, and potential impairment charges related to its long-lived assets. Based on its evaluation, the Company determined that its long-lived assets were impaired as of March 31, 2023, and it recognized an impairment charge of $0.4 million related to its long-lived assets for the three months ended March 31, 2023. The Company may incur additional costs not currently contemplated due to events that may occur because of, or that are associated with, the Restructuring.

The following table summarizes the activity related to the restructuring liabilities included in accrued liabilities on the condensed consolidated balance sheet associated with our restructuring initiatives for the three months ended March 31, 2023 (in thousands):

	March 31, 2023
Balance as of December 31, 2022	$ —
Restructuring, impairment and related charges	1,483
Cash payments	(542)
Noncash activities	(470)
Balance as of March 31, 2023	$ 471

5. Balance Sheet Components

Inventory

Inventories consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Raw materials	$ 5,078	$ 2,461
Work-in-process	4,064	4,191
Finished goods	2,597	3,334
Total inventories	11,739	9,986
Less: long-term inventories	(3,725)	(1,559)
Total current inventories	$ 8,014	$ 8,427

Inventory amounts written down to net realizable value in the consolidated statements of operations and comprehensive loss included a charge of $0.8 million to cost of goods sold during the three months ended March 31, 2023, related to excess and obsolescence reserves associated with Trudhesa.

The Company classifies its inventories based on its anticipated levels of sales, any inventory in excess of its normal operating cycle is classified as long-term within Other Assets on its consolidated balance sheets.

Prepaid Expenses and Other Current Assets

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

	March 31, 2023	December 31, 2022
Other prepaids	$ 1,006	$ 1,587
Other current assets	680	649
Prepaid insurance	426	1,036
Tax refund receivable	13	12
Total prepaid expenses and other current assets	$ 2,125	$ 3,284

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Accrued compensation	$ 3,493	$ 5,287
Accrued sales discounts and allowances	3,278	3,376
Accrued other liabilities	2,838	1,662
Accrued professional services	1,948	1,808
Accrued construction in progress	166	370
Total accrued liabilities	$ 11,723	$ 12,503

6. Commitments and Contingencies

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. The Company did not accrue any costs as of March 31, 2023 and December 31, 2022, as no contingent liabilities were deemed to be probable.

7. Leases

Real Estate Leases

In April 2022 the Company entered into a non-cancelable operating lease for 8,045 square feet of office space. Rent is payable monthly, increasing by approximately 2.5% each year. The term of the lease is 127 months, and commenced in the first quarter of 2023. Upon commencement, the Company recorded a right-of-use asset and a lease liability on the Condensed Consolidated Balance Sheet.

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. The initial term of the lease was 3 years and the Company renewed the lease for an additional four years with an expiration date of August 31, 2024.

Commercial Fleet Leases

During 2022 and in first quarter 2023, the Company took delivery of a portion of its commercial car fleet for its salesforce. Each commercial fleet lease has a term of 12 months including options to renew for a total of 54 months, we believe a total of 36 months is deemed reasonable to exercise. In addition, the Company can terminate the vehicle leases at any time without a significant penalty. For the discount rate used in the commercial fleet lease, the Company used the weighted-average rate implicit in the commercial fleet leases.

As of March 31, 2023, the Company was not party to any finance leases.

The following table reconciles the Company's undiscounted operating lease cash flows to its operating lease liability (in thousands):

	March 31, 2023
Remaining 2023	$ 1,477
2024	1,713
2025	766
2026	288
2027	1,829
Total undiscounted cash flows	6,073
Less: imputed interest	(1,263)
Total lease liabilities	4,810
Less: current portion	(1,736)
Lease liabilities	$ 3,074

The weighted average remaining lease term and the weighted average discount rate used to determine the operating lease liability were as follows:

	March 31, 2023
Weighted average remaining lease term (years)	4.8
Weighted average discount rate	7.6 %

Operating lease expense was $0.5 and $0.3 million for the three months ended March 31, 2023 and 2022, respectively. Variable lease expense was $0.1 million for operating leases during the three months ended March 31, 2022. Rent expense recognized for short term leases was $0.1 million for the three months ended March 31, 2022. The Company did not incur any variable lease expense and rent expense for short term leases for the three months ended March 31, 2023.

8. Long-Term Obligations

Oaktree Loan and Security Agreement

On March 17, 2022 (“Closing Date”), the Company entered into a Senior Credit Agreement with Oaktree Fund Administration, LLC as administrative agent, and the lenders party thereto (collectively “Oaktree”) under which it borrowed $50.0 million.

The term loan has a maturity date of March 17, 2027, initially bearing interest at the Secured Overnight Financing Rate (“SOFR”) + 8.75% (with a SOFR floor of 1.00%). Once Trudhesa achieves at least $125.0 million in net sales over a trailing 12-month period, interest will step down to SOFR + 8.00% (with a SOFR floor of 1.00%). The Company is required to make quarterly interest-only payments until the fourth anniversary of the Closing Date, after which the Company is required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. Prepayments of the loan, in whole or in part, will be subject to early prepayment fee which declines each year until the fourth anniversary date of the Closing Date, after which no prepayment fee is required. The Company is also required to pay an exit fee upon any payment or prepayment equal to 2.0% of the aggregate principal amount of the loans funded under the Senior Credit Agreement. The Senior Credit Agreement contains customary representations, warranties and events of default. If the Company defaults under its Senior Credit Agreement, the lenders may accelerate all of the Company's repayment obligations and take control of its pledged assets. The lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect as defined under the Senior Credit Agreement and the Revenue Interest Financing Agreement, thereby requiring the Company to repay the loans immediately or to attempt to reverse the lenders’ declaration through negotiation or litigation. Among other loan covenant requirements, the Senior Credit Agreement also requires the Company to provide an audit opinion of its annual financial statements not subject to any "going concern" or like qualification or exception or explanatory paragraph of going concern footnote. On March 22, 2023, the Company entered into a letter agreement with Oaktree in connection with its Senior Credit Agreement, to obtain a waiver from Oaktree for any default or event of default arising from the going concern explanatory paragraph included in the report of its Independent Registered Public Accounting Firm on its audited consolidated financial statements for the year ended December 31, 2022. Under the Senior Credit Agreement, the Company is subject to a minimum liquidity requirement of $12.5 million unrestricted cash balance at all times.

The Company identified a number of embedded derivatives that require bifurcation from the term loan and that were separately accounted for in the consolidated financial statements as one compound derivative liability. Certain of these embedded features include change in control provisions, events of default and contingent rate increases and were determined to qualify as an embedded derivative under ASC 815-40. The embedded derivative and the term loan obligation have been netted to result in a net embedded derivative liability and is classified as a Level 3 financial liability in the fair value hierarchy as of March 31, 2023. The fair value of the embedded derivative liabilities associated with the term loans was estimated using the discounted cash flow method under the income approach. This involves significant Level 3 inputs and assumptions including an estimated probability and timing of a change in control and events of default (see Note 3 for additional details). The Company re-evaluates this assessment each reporting period and records any gains or losses in other income (expense). The initial recognition of the embedded derivative liability upon issuance of the Oaktree term loan was $0.4 million and is included in the term loan obligation in the consolidated Balance Sheets. At March 31, 2023 and December 31, 2022 the fair value of the embedded derivative liability was $0.4 million and $0.6 million, respectively.

In connection with the issuance of the term loan, the Company recorded debt discount and debt issuance costs of $2.9 million. The discount and issuance costs are amortized over the life of the term loan. Interest expense for the three months ended March 31, 2023 and 2022 was $1.6 million and $0.2 million, respectively, and is inclusive of non-cash amortization of the debt discount and debt issuance costs and accretion of final payment. The fair value of the term loan at March 31, 2023 and December 31, 2022 was $52.2 million and $51.9 million, respectively.

A portion of the loan proceeds were used to repay in full the $32.9 million aggregate principal amount (including the prepayment fee and final payment fee) of loans outstanding owed to Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB” and together with Oxford, the “Prior Lenders”) by the Company in the first quarter of 2022.

Deferred Royalty Obligation

On March 17, 2022, the Company entered into a Revenue Interest Financing Agreement (“RIF” or “Deferred Royalty Obligation”) with certain purchasers party thereto (collectively “Purchasers”) and Oaktree Fund Administration, LLC as administrative agent, pursuant to which the Company sold to the Purchasers the right to receive payments from us at a tiered percentage (the “Applicable Tiered Percentage”), of future net revenues of Trudhesa, including worldwide net product sales and upfront payments, and milestones, (collectively, “the Revenue Interests”). Under the terms of the agreement, the Company received $50.0 million (“Investment Amount”), less transaction expenses, in exchange for tiered royalty payments on worldwide net sales from Trudhesa, as follows: 7.75% on annual United States net sales up to $150.0 million; 4.75% on annual United States net sales between $150 million and $300 million; 0.75% on

annual United States net sales greater than $300.0 million; and 10% of any upfront payments, milestone payments and royalties received by us from licensing or partnerships relating to Trudhesa outside the United States.

The Purchaser's rights to receive the Revenue Interests shall terminate on the date on which the Purchasers have received payments equal to 175% of the funded portion of the Investment Amount including the aggregate of all payments made to the Purchasers as of such date, unless the Revenue Interest Financing Agreement is earlier terminated. If the Purchasers have not received payments equal to the 175% of the funded portion of the Investment Amount by the nine-year anniversary of the initial closing date, among other things, the Company shall pay the Purchasers an amount equal to the funded portion of the Investment Amount plus a specific annual rate of return less payments previously received.

Under the RIF, the Company has an option (the "Call Option") to repurchase future Revenue Interests at any time until the third anniversary of the Closing Date upon advance written notice. Additionally, the Purchasers have an option (the "Put Option") to terminate the RIF and to require the Company to repurchase future Revenue Interests upon enumerated events such as a bankruptcy event, a material adverse effect or a change of control. If the Put Option or the Call Option are exercised, the required repurchase price is (i) as of any date before the one-year anniversary of the Closing Date, an amount equal to (a) 1.25 multiplied by (b) the Investment Amount, (ii) as of any date on or after the one-year anniversary of the Closing Date and before the two-year anniversary of the Closing Date, an amount equal to (a) 1.40 multiplied by (b) the Investment Amount, (iii) as of any date on or after the two-year anniversary of the Closing Date and before the three-year anniversary of the Closing Date, an amount equal to (a) 1.55 multiplied by (b) the Investment Amount, and (iv) as of any date on or after the three-year anniversary of the Closing Date, an amount equal to (a) 1.75 multiplied by (b) the Investment Amount, in each case net of the sum of any payments received by the Purchasers prior to such Put Option Closing Date or Call Option Closing Date, as applicable.

If the Purchasers have not received 100% of the Investment Amount by February 15, 2027, the first tier royalty rate will be subject to an increase from 7.75% to 10.75%. As of March 31, 2023, the Company has made $0.9 million in payments to the Purchasers. The Company's obligations under the RIF are secured, subject to customary permitted liens and other agreed upon exceptions and subject to an intercreditor agreement with Oaktree Fund Administration, LLC, as administrative agent for the lenders under the Senior Credit Agreement, by a perfected security interest in (i) accounts receivable arising from net sales of Trudhesa and (ii) intellectual property that is claiming or covering Trudhesa, or any method of using, making or manufacturing Trudhesa, including regulatory approvals, clinical data and all other Trudhesa assets.

The Company evaluated the terms of the deferred royalty obligation and concluded that the features of the Investment Amount are similar to those of a debt instrument. Accordingly, the Company accounted for the transaction as long-term debt recorded at amortized cost using the effective interest method. The Company further evaluated the terms of the debt and determined that the Put Options under the RIF that are exercisable by Purchasers upon certain contingent events were determined to be embedded derivatives requiring bifurcation and separately accounted for as a single compound derivative instrument (see Note 3). The Put Option has been determined to qualify as an embedded derivative under ASC 815-40. The embedded derivative and the deferred royalty obligation have been netted to result in a net embedded derivative liability as of March 31, 2023 and December 31, 2022. The embedded derivative is classified as a Level 3 financial liability in the fair value hierarchy. The Company determined the fair value of the derivative using an option pricing Monte Carlo simulation model taking into account the probability of change of control or event of default occurring and potential repayment amounts and timing of such payments that would result under various scenarios, as further described in Note 3, "Fair Value of Financial Instruments". The Company recorded the initial fair value of the derivative liability of $1.5 million which was included in the deferred royalty obligation in the consolidated Balance Sheet. The Company remeasures the derivative liability to fair value each reporting period until the termination of the RIF. At March 31, 2023 and December 31, 2022 the fair value of the derivative liability is $14.0 million and $11.0 million, respectively.

The effective interest rate as of March 31, 2023 was 10.4%. In connection with the deferred royalty obligation, we incurred debt issuance costs totaling $1.4 million. Debt issuance costs have been netted against the deferred royalty obligation and are being amortized over the estimated term of the debt using the effective interest method, adjusted on a prospective basis for changes in the underlying assumptions and inputs. The assumptions used in determining the expected repayment term of the obligation and amortization period of the issuance costs requires that we make estimates that could impact the short and long-term classification of these costs, as well as the period over which these costs will be amortized.

The Company periodically assesses the amount and timing of expected royalty payments using a combination of internal projections and forecasts from external sources. The estimates of future net product sales (and resulting royalty payments) are based on key assumptions including population, penetration, probability of success, and sales price, among others. To the extent such payments are greater or less than the Company's initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the deferred royalty obligations and the effective interest rate. Interest expense recognized for the three months ended March 31, 2023 and 2022, $1.3 million and $0.3 million, respectively. The fair value of the deferred royalty obligation at March 31, 2023 and December 31, 2022 is $50.4 million and $48.9 million, respectively, inclusive of the fair value of the derivative liability.

Oxford and Silicon Valley Bank Term Loan

In July 2021, the Company entered into the Loan Agreement with the "Prior Lenders", to lend the Company up to an aggregate of $50.0 million in a series of term loans (the "Term Loan"). The term loans accrued 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% and were subject to a prepayment fee of 1.0% to 3.0% depending upon when the prepayment occurs. On repayment of the Term Loans, the Company was required to make a final payment fee to the Prior Lenders equal to 6.5% of the original principal amount of the Term Loans.

On March 17, 2022, upon entering into the Senior Credit Agreement, the Company repaid the $30.0 million of outstanding principal, interest, including prepayment and final payment fees owed under the Loan Agreement to the Prior Lenders. The Company recorded a loss of $3.3 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 interest expense, net in the consolidated statement of operations and other comprehensive loss. Interest expense for the three months ended March 31, 2022 was $0.7 million and was inclusive of non-cash amortization in the amount of $0.2 million related to the amortization of the debt issuance costs and accretion of final payment.

In connection with entering into the Loan Agreement and borrowings under the agreement, the Company issued warrants to purchase 71,522 and 23,166, shares of its common stock, respectively, to the Prior Lenders at a per share exercisable price of $8.39 per share and $12.95 per share, respectively, all with ten year terms.

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:

	March 31, 2023	December 31, 2022
Stock incentive plans	7,779,248	6,351,263
Exercise of common stock warrants	94,688	94,688
Total	7,873,936	6,445,951

Open Market Sales Agreement

In May 2022, the Company entered into a sales agreement with Cowen and Company, LLC, as a sales agent, pursuant to which the Company may offer and sell shares of its common stock, from time to time, up to an aggregate amount of gross sales proceeds of $50.0 million through an at-the-market Program (the "2022 ATM Program"), under the 2022 Shelf Registration Statement. As of March 31, 2023, $45.0 million in shares of common stock remain eligible for sale under the 2022 ATM Program.

10. Stock Incentive Plans

As of March 31, 2023, the Company's equity incentive plans authorized a total of 7,779,248 shares, of which 2,746,359 shares are available for future grant, and 5,065,389 shares are outstanding.

The Company's 2021 Stock Incentive Plan, (the "2021 Plan"), provides for annual increase in the number of shares that may be issued under the 2021 Plan 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's Employee Stock Purchase Plan (the "ESPP"), provides for annual increase in the number of shares that may be issued under the 2021 Plan 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.

Effective January 1, 2023, the 2021 Plan and ESPP reserves increased by 1,186,965 shares and 237,393 shares, respectively. Changes in shares available for grant under the 2021 Plan during the three months ended March 31, 2023 were as follows:

	Shares Available for Grant
Shares available for grant at December 31, 2022	1,837,854
2021 Plan reserve increase January 1, 2023	1,186,965
ESPP reserve increase January 1, 2023	237,393
Options and restricted units granted	(865,920)
Options and restricted units forfeited, cancelled, or expired	350,067
Shares available for grant at March 31, 2023	2,746,359

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2023	2022
Cost of goods sold	$ 17	$ 31
Research and development	170	411
Selling, general and administrative	1,132	1,353
Total stock-based compensation expense	$ 1,319	$ 1,795

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 stock for those stock options that had exercise prices lower than the fair value of the Company's common stock at March 31, 2023.

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			
	Number of Options	Weighted -Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance — December 31, 2022	4,275,909	$ 8.08	7.5	$ 1,038
Authorized	—			
Granted	865,920	2.30		
Exercised	—	—		
Cancelled	(313,940)	7.91		
Balance — March 31, 2023	4,827,889	$ 7.18	7.3	$ 2
Exercisable — March 31, 2023	2,491,654	$ 7.00	5.7	$ 2

As of March 31, 2023, there was $10.2 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 2.6 years.

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 March 31,	
	2023	2022
Expected term (in years)	6.1	6.1
Expected volatility	70.7%-71.3	72.9 %
Risk-free interest rate	3.7% -3.95%	1.70% - 1.98%
Expected dividends	—	—

Restricted Stock Units

During 2021, the Compensation Committee of the Board of Directors approved the Trudhesa Launch Equity Incentive Plan for awards of performance-based restricted stock units ("PSUs") to certain senior executives of the Company. Each award reflects a target number of shares ("Target Shares") that may be issued to the award recipient. These awards may be earned upon the completion of two-year performance periods ending December 31, 2022, and December 31, 2023. Whether units are earned at the end of the performance period will be determined based on the achievement of certain revenue targets over the performance period. The PSUs also include a performance objective relating to total shareholder return ("TSR"). TSR reflects the change in the value of the Company's common stock over each performance period. Depending on the revenue achieved and the TSR during the two-year performance periods, the actual number of shares that a grant recipient receives at the end of the performance period may range from 0% to 125% of the Target Shares granted for the 2022 performance period and 0% to 150% of the Target Shares granted for the 2023 performance period.

In the period it becomes probable that the minimum threshold specified in the award will be achieved, we recognize expense for the proportionate share of the total fair value of the PSUs related to the vesting period that has already lapsed for the shares expected to vest and be released. The remaining fair value of the shares expected to vest and be released is expensed on a straight-line basis over the balance of the vesting period. In the event the Company determines it is no longer probable that we will achieve the minimum threshold specified in the award, we reverse all of the previously recognized compensation expense in the period such a determination is made.

The fair value of the Target Shares and restricted stock awards are based on the fair value of the underlying shares on the date of grant. The fair value of the portion of the Target Shares that relate to a relative TSR performance objective was determined using a Monte Carlo simulation analysis to estimate the total shareholder return ranking of the Company among a peer group over the remaining performance periods. The expected volatility of the Company's common stock at the date of grant was estimated based on the average historical volatilities for comparable publicly traded pharmaceutical companies. The Company used an expected dividend yield of zero. The risk-free interest rate assumption was based on observed interest rates consistent with the approximate two-year performance measurement period.

The fair value of PSUs granted to employees was estimated at the date of grant using the following assumptions:

	December 31, 2021
Contractual term (in years)	2.1
Expected volatility	0.83 %
Risk-free interest rate	0.70 %
Expected dividends	—

As of March 31, 2023, the Company does not expect these PSUs to vest, therefore there was no unrecognized compensation expense. There were no PSUs that vested during the three months ended March 31, 2023 and 205,000 and 237,500 PSUs are outstanding as of March 31, 2023 and December 31, 2022, respectively.

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 three months ended March 31, 2023 and 2022 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 months ended March 31, 2023, 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 Internal Revenue Code. 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 months ended March 31, 2023 and 2022, the amount expensed under the plan was $0.3 million and $0.2 million, respectively.

13. Net Loss Per Share

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

	Three Months Ended March 31,	
	2023	2022
Stock options to purchase common stock	4,827,889	4,060,283
Non-vested PSUs	205,000	485,571
Warrants to purchase common stock	94,688	94,688
Total	5,127,577	4,640,542

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 with our audited financial statements and related notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K.

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 biopharmaceutical company with a mission to develop 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 space 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. In September of 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.

We have retained all development and commercial rights to Trudhesa. Given the concentrated prescriber base of our target market for Trudhesa, we independently launched in October of 2021. Trudhesa was launched with an initial sales force of 60 representatives and expanded to approximately 90 representatives in the third quarter of 2022 to support our targeted launch strategy. The sales team is supported by an established market access, medical affairs, marketing, and operations infrastructure. Our commercial efforts are focused on approximately 11,000 high value healthcare professionals targets that prescribe approximately 40% of all migraine prescriptions and 73% of all acute branded total prescriptions. Importantly, we have secured managed care contracts providing access to Trudhesa for greater than 80% of commercial lives in the United States. We have deployed a robust sample program to ensure trial with Trudhesa for patients seeking better treatments and outcomes. Through both our commercial and medical affairs infrastructure we have engaged healthcare practitioners and patients, partnered with national associations and actively supported advocacy groups in the migraine market. These efforts have been, and will continue to be, supplemented with non-personal promotion to all targeted and non-targeted medium value physicians. To capture the maximum commercial opportunity of Trudhesa, we may also selectively seek partners to commercialize the product outside of our target markets, including additional penetration within the broader primary care setting, as well as in geographies outside of the United States. Through March 31, 2023, there have been approximately 81,400 prescriptions of Trudhesa generated since launch and, based on third-party data, we believe Trudhesa accounts for approximately 4.7% of total branded acute migraine prescriptions among over 2,700 unique Trudhesa prescribers since launch. Additionally, based on internal data, approximately 63% of new Trudhesa patients eligible for a refill have received a second prescription.

On February 22, 2023, we announced plans to reduce our workforce by approximately 16% and incurred a charge of approximately $1.5 million primarily consisting of severance costs, employee-related benefits, supplemental one-time termination payments, and asset write-downs in the first quarter of 2023. We plan to reprioritize spend to capitalize on the continued positive momentum in payor and prescriber uptake of Trudhesa and halt research and development efforts on our prior product candidate INP105 to address acute agitation and aggression in autism spectrum disorder.

Prior to February 2023, we had built out an internal research and development team and also used third-party contract research organizations, or CROs, to carry out preclinical and clinical development. We relied on third-party contract manufacturing organizations, or CMOs, to manufacture and supply our clinical materials to be used during the development of any future 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.

Through March 31, 2023, we have funded our operations primarily through proceeds from the sale of equity securities, including proceeds from the sale and issuance of common stock, proceeds pursuant to a Revenue Interest Financing Agreement ,or RIF, that we entered into in March 2022 with certain purchasers party thereto and Oaktree Fund Administration, LLC as administrative agent, redeemable convertible preferred stock, warrants, debt and convertible notes. We have incurred significant operating losses to date. Our net losses were $30.1 million and $27.0 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $351.2 million and a cash balance of $35.5 million.

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 fully launched Trudhesa in October of 2021 and will continue to evaluate trends related to revenue momentum for Trudhesa. At launch we implemented our "bridge and co-pay savings" program which we believe provides an affordability solution for patients that enables higher physician prescribing. The program only provides assistance to commercially insured patients. Our data suggests these programs are playing an important role in supporting demand for Trudhesa.

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, adjustments to net realizable value, 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 any future 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 any future product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained.

Prior to our strategic reprioritization in February 2023, we tracked our direct costs by product candidate, but we do not allocate overhead costs or certain external costs because they supported multiple future product candidates. In particular, with respect to internal costs, several of our departments supported multiple future product candidate research and development programs, and we do not allocate those costs by 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 2021, we expect our selling and marketing costs will continue to remain significant as we continue to support our commercial activities associated Trudhesa. We continue to incur 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 Income (Expense), Net

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

Consolidated Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

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

	Three Months Ended March 31,		Change
	2023	2022	
	(in thousands)		
Product revenue, net	$ 4,372	$ 1,759	$ 2,613
Cost of goods sold	2,285	1,033	1,252
Gross profit	2,087	726	1,361
Operating expenses:			
Research and development	3,003	3,650	(647)
Selling, general and administrative	22,037	19,799	2,238
Restructuring	1,483	—	1,483
Total operating expenses	26,523	23,449	3,074
Loss from operations	(24,436)	(22,723)	(1,713)
Interest income (expense), net	(2,933)	(4,427)	1,494
Other income (expense), net	(2,698)	180	(2,878)
Total other income (expense), net	(5,631)	(4,247)	(1,384)
Loss before income taxes	(30,067)	(26,970)	(3,097)
Provision for income taxes	—	—	—
Net loss and comprehensive loss	$ (30,067)	$ (26,970)	$ (3,097)

Product revenue, net

Net product revenue was $4.4 million for the three months ended March 31, 2023, compared to $1.8 million for the three months ended March 31, 2022. The increase of $2.6 million in net product revenue is due to both increased Trudhesa sales volume and improvements in net price realization due to decreases in the bridge and co-pay savings program discount during the three months ended March 31, 2023, compared to the three months ended March 31, 2022. Sales allowances and accruals mostly consisted of the bridge and co-pay savings program discounts, managed care rebates and distribution fees.

Cost of goods sold

Cost of goods sold of $2.3 million for the three months ended March 31, 2023 compared to $1.0 million for the three months ended March 31, 2022 is related to manufacturing, conversion and packing costs related to the cost of Trudhesa products sold, in addition to certain overhead costs. For the three months ended March 31, 2023, we recorded a $0.8 million charge related to excess and obsolescence reserves associated with Trudhesa.

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, referred to as zero cost inventories, and are therefore excluded from the cost of goods sold in the three months ended March 31, 2022. We sold all remaining zero cost inventories in 2022.

Research and Development

Research and development expenses were $3.0 million for the three months ended March 31, 2023, compared to $3.7 million for the three months ended March 31, 2022. The decrease of $0.7 million is primary due to decreased personnel costs and program costs as we redirected our resources from research and development activities and pivoted our focus to supporting our commercial operations rather than research and development in the first quarter of 2023. As a result of this strategic reprioritization we expect our research and development expense to decrease for the remainder of 2023 as compared to 2022.

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

	Three Months Ended March 31,		
	2023	2022	Change
	(in thousands)		
Program-specific costs:			
Trudhesa	$ 300	$ 469	$ (169)
INP105	755	639	116
Total program-specific costs	1,055	1,108	(53)
Non program-specific costs:			
Personnel-related	$ 1,808	$ 2,353	$ (545)
Internal, overhead and other expenses	140	189	(49)
Total non program-specific costs	1,948	2,542	(594)
Total research and development expenses	$ 3,003	$ 3,650	$ (647)

Selling, General and Administrative

Selling, general and administrative expenses were $22.0 million for the three months ended March 31, 2023, compared to $19.8 million for the three months ended March 31, 2022. The increase of $2.2 million was primarily due to increased commercial operations and sales and increased promotional and marketing spend of $2.5 million in the three months ended March 31, 2023 compared to the same period in 2022, partially offset by lower medical affairs spend of $0.3 million in three months ended March 31, 2023 compared to the same period in 2022. Administrative expenses remained flat in the three months ended March 31, 2023 compared to the same period in 2022.

Restructuring

Restructuring expenses were $1.5 million for the three months ended March 31, 2023 and represent one-time termination benefits and contractual termination benefits for severance costs related to the reduction in force and impairment charges related to our long-lived assets. There were no restructuring expenses for the three months ended March 31, 2022.

Interest income (expense), net

Interest income (expense), net was an expense of $2.9 million for the three months ended March 31, 2023, compared to expense of $4.4 million for the three months ended March 31, 2022. The decrease in expense of $1.5 million was due to the absence of debt extinguishment costs of $3.3 million incurred in the three months ended March 31, 2022, partially offset by $1.8 million of higher interest expense related to our Oaktree term loan and RIF for the three months ended March 31, 2023.

Other Income (Expense), Net

Other income (expense), net was an expense of $2.6 million for the three months ended March 31, 2023, compared to income of $0.2 million for the three months ended March 31, 2022. The increase in expense of $2.9 million was primarily due to an increase in the fair value of the Oaktree term loan and RIF derivatives of $2.9 million related to changes in expectations of timing and probability of an event of default and occurrence of a change in control.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. Through March 31, 2023, we have funded our operations primarily through the issuance of common stock, proceeds pursuant to the RIF, convertible promissory notes, redeemable convertible preferred stock, debt, and warrants with aggregate proceeds of $397.8 million. As of March 31, 2023, we had available cash and cash equivalents of $35.5 million and an accumulated deficit of $351.2 million.

We have an effective shelf registration statement on Form S-3 filed with the SEC in May 2022, or the 2022 Shelf Registration, pursuant to which we registered for sale up to $200 million of any combination of our common stock, preferred stock, debt securities, warrants, subscription rights and/or units from time to time and at prices and on terms that we may determine. In May 2022, we entered into a sales agreement with Cowen and Company, LLC, as a sales agent, pursuant to which we may offer and sell shares of our common stock, from time to time, up to an aggregate amount of gross sales proceeds of $50.0 million through an at-the-market program or the 2022 ATM program under the 2022 Shelf Registration. In July 2022, we sold 542,500 shares of common stock at a weighted-average price per share of $9.25 pursuant to the 2022 ATM Program and received proceeds of approximately $4.5 million, net of commissions and fees. As of March 31, 2023, $45.0 million in shares of common stock remain eligible for sale under the 2022 ATM Program.

Based upon our current operating plan, we estimate that our cash and cash equivalents as of March 31, 2023, are insufficient for us to fund operating, investing, and financing cash flow needs for twelve months subsequent to the issuance date of the financial statements as of and for the period ended March 31, 2023 and accordingly, we have determined that there is substantial doubt about our ability to continue as a going concern.

Our loan agreement with Oaktree includes covenants requiring us to provide an audit opinion on our annual financial statements that is not subject to any "going concern" or like qualification or exception (see Note 8—Debt for more information about our long-term obligations). On March 22, 2023, we entered into the Oaktree Letter Agreement in connection with our Senior Credit Agreement, to obtain a waiver from Oaktree of any default or event of default arising from the going concern explanatory paragraph included in the report of its Independent Registered Public Accounting Firm on its audited consolidated financial statements for the year ended December 31, 2022. The Senior Credit Agreement also requires us to maintain a minimum $12.5 million unrestricted cash balance at all times. We plan to address this condition in the second quarter of 2023, either through additional equity financings or through other capital sources, including collaborations with other companies or other strategic transactions. To the extent that we may need to raise additional funds by issuing equity securities, our stockholders may experience significant dilution. If sufficient funds on acceptable terms are not available when needed, we could be required to reduce operating expenses and reduce the scope of our commercialization plans for Trudhesa. Failure to manage discretionary spending or raise additional financing, may adversely impact our ability to achieve our intended business objectives. Our unaudited condensed consolidated financial statements as of and for the period ended March 31, 2023 do not include any adjustments that might result from the unfavorable outcome of this uncertainty.

Cash Flows

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Cash used in operating activities	$ (24,143)	$ (24,211)
Cash used in investing activities	(1,046)	(8)
Cash provided by financing activities	—	65,844
Net increase (decrease) in cash and cash equivalents	$ (25,189)	$ 41,625

Cash Flows From Operating Activities

For the three months ended March 31, 2023, cash used in operating activities was $24.1 million, which consisted of a net loss of $30.1 million and an increase of $1.1 million in net current assets partially offset by $7.0 million in non-cash charges. The $1.1 million net cash outflow related to changes in our current and non-current assets and liabilities and was attributed to an increase in inventories, operating leases and a decrease in accrued liabilities of $3.4 million, partially offset by a decrease in accounts receivables and prepaid expenses and other current assets of $2.3 million. The non-cash charges primarily consisted of a change in the fair value of our derivative liabilities, stock-based compensation, depreciation and amortization, amortization of debt discount, inventory write-downs to net realizable value, long-lived asset impairments, and a change in the fair value of our warrant liabilities.

For the three months ended March 31, 2022, cash used in operating activities was $24.2 million, which consisted of a net loss of $27.0 million and an increase of $3.1 million in net current assets partially offset by $5.9 million in non-cash charges. The $3.1 million net cash outflow related to changes in our net current assets and was attributed to an increase in accounts receivables, inventories and prepaid assets of $6.0 million offset by an increase in accounts payable and accrued liabilities of $2.9 million due primarily to an increase in the level of selling, general and administrative expenses. The non-cash charges primarily consisted of a loss on early extinguishment of debt, stock-based compensation, depreciation, amortization of debt discount and issuance costs, and a change in the fair value of our warrant liabilities.

Cash Flows From Investing Activities

For the three months ended March 31, 2023 and 2022, cash used in investing activities of $1.0 million and $8,000, respectively, and was related to purchases of property and equipment.

Cash Flows From Financing Activities

There were no financing activities in the three months ended March 31, 2023.

For the three months ended March 31, 2022, cash provided by financing activities was $65.8 million, consisting primarily of net proceeds received from the Oaktree Financing and Revenue Interest Financing resulting in proceeds of $98.6 million, net of debt issuance costs and discount, partially offset by the repayment of the Oxford and Silicon Valley Bank loan of $32.9 million including the final payment and prepayment fee.

Funding Requirements

We use our cash to fund operating expenses, including research and development expenditures and commercialization expenses for Trudhesa. We incur significant commercialization expenses for product sales, marketing and outsourced manufacturing with respect to Trudhesa. On February 22, 2023, we announced plans to reduce our workforce by approximately 16%. These actions reflect our determination to reprioritize spend to capitalize on the continued positive momentum in payor and prescriber uptake of Trudhesa and as a result we halted research and development efforts on INP105 to address acute agitation and aggression in autism spectrum disorder. We recorded a restructuring charges of $1.5 million in the aggregate primarily consisting of severance costs, employee-related benefits, supplemental one-time termination payments, and asset write-downs in the first quarter of 2023.

Even in light of the reduction in workforce, we expect to continue to incur significant expenses and operating losses for the foreseeable future. Based on our cash and cash equivalents on hand of approximately $35.5 million at March 31, 2023, we estimate that we will need to raise additional capital in the second quarter of 2023 to avoid defaulting under the Senior Credit Agreement. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs primarily through equity 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 future product candidates for which we receive marketing approval;
- the number and development requirements of any future product candidates that we may pursue;
- the costs associated with building out our operations;
- the revenue, if any, received from commercial sales of any future 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 any future product candidates, if approved, and existing and potential future therapies that compete with any future product candidates; and
- the costs associated with being a public company.

If we do raise additional capital through public or private equity 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.

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.

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 our Annual Report on Form 10-K for the year ended December 31, 2022.

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.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in the section of this report captioned “Risk Factors.” The following is a summary of the principal risks we face:

- 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 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.
- The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for additional product candidates.
- Our future commercial success depends upon attaining significant market acceptance of any future product candidates, if approved, among physicians, patients, health care payors and others in the medical community necessary for commercial success.
- Clinical failure may occur at any stage of clinical development, and we may never succeed in developing and commercializing additional marketable product candidates or generating additional product revenue.
- Delays in the commencement, enrollment or completion of clinical trials of any future 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 future product candidates on a timely basis, or at all.
- We rely entirely on third parties for the manufacturing of Trudhesa and any future 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, and any future product candidates, our ability to commercialize such product candidates, if approved, would be impaired.
- If we are not able to obtain and enforce patent protection for our technologies or any future product candidates, development and commercialization of our technology and any future product candidates may be adversely affected.
- We may be required to expand our operations capabilities in the future, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop and commercialize any future product candidates.

- The ongoing COVID-19 pandemic, 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 any future product candidates.
- The market price of our common stock may be volatile, which could result in substantial losses for investors.

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. To date, we have financed our operations primarily through the sale and issuance of redeemable convertible preferred stock, convertible notes and warrants, common stock offerings, debt financings and royalty financings. Since 2021, we have also relied on revenues generated from net sales of Trudhesa.

We have incurred significant net losses since our inception. Our net losses were $30.1 million and $106.3 million for the three months ended March 31, 2023 and the year ended December 31, 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $351.2 million. We cannot predict when or whether we will become profitable and we may never be able to develop or commercialize any future product candidates. 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 product candidates, our expenses could increase substantially. Although we have 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 such product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for product candidates in those markets.

Our expenses and net losses may increase as we continue to commercialize Trudhesa, continue our development of, and seek regulatory approvals for, 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 expand the market for Trudhesa, 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.

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 March 31, 2023, we had $35.5 million of cash and cash equivalents. Based upon our current operating plan, we estimate that our cash and cash equivalents as of March 31, 2023, are insufficient for us to fund operating, investing, and financing cash flow needs for twelve months subsequent to the issuance date of the financial statements included in this Quarterly Report on Form 10-Q and accordingly, we have determined that there is substantial doubt about our ability to continue as a going concern. Based on our cash and cash equivalents on hand as of March 31, 2023, we estimate that we will need to raise additional capital in the second quarter of 2023 to avoid defaulting under the Senior Credit Agreement. We believe that we will continue to expend substantial resources for the foreseeable future as we continue the commercialization of Trudhesa, develop additional product candidates, if any, and launch clinical trials for such product candidates and pursue commercialization of 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 product candidates. Our costs will increase if we suffer any delays in our planned clinical trials for our current product candidates. 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. 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 product candidates if clinical trials are successful;
- the scope, progress, results and costs of developing and advancing 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 product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- the amount of revenue from Trudhesa and any other 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. While we are currently engaged in efforts to bring in additional capital, such efforts may not be successful or result in sufficient capital to realize our business plans and goals. 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 if available, 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 product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to continue to commercialize Trudhesa and other future 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 with Oaktree includes covenants requiring us to provide an audit opinion of our annual financial statements that is not subject to any "going concern" or like qualification or exception and requires us to maintain a minimum $12.5 million unrestricted cash balance at all times. On March 22, 2023, we entered into a letter agreement with Oaktree (the "Oaktree Letter Agreement") in connection with our Senior Credit Agreement, to obtain a waiver from Oaktree of any default or event of default arising from the going concern explanatory paragraph included the report of its Independent Registered Public Accounting Firm on its audited consolidated financial statements for the year ended December 31, 2022. Further, our loan agreement with Oaktree is secured by a lien on substantially all of our assets, and our revenue interest financing agreement Oaktree is secured by accounts receivable arising from net sales of Trudhesa and our intellectual property relating to Trudhesa. If we raise additional funds through strategic partnerships or royalty monetization agreements 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 when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for any future 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:

- quarterly fluctuations in product sales of Trudhesa or any other product candidates which may receive regulatory approval;
- variation in the level of expense related to the commercialization of Trudhesa or any other product candidates that receives regulatory approval;
- variations in the level of expense related to the ongoing development of 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 future product candidates receive regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting any future product candidates or those of our competitors; and
- changes in general market and macroeconomic 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.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions, including formerly with Silicon Valley Bank, in excess of the FDIC insurance limit and similar regulatory insurance limits outside the United States. Further, if we enter into a credit, loan or other similar facility with a financial institution, certain covenants included in such facility may require as security that we keep a significant portion of our cash with the institution providing such facility. If a depository institution where we maintain deposits fails or is subject to adverse conditions in the financial or credit markets, we may not be able to recover all, if any, of our deposits, which could adversely impact our operating liquidity and financial performance.

Risks Related to Commercialization of Trudhesa and Any Future Product Candidates

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

Trudhesa, and any product candidates for which we receive regulatory approval in the future 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, calcitonin gene-related peptides antagonists, or gepants, lasmiditan and alternative formulations of DHE, such as Migranal, which is also administered intranasally. All of these are 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 Trudhesa and any future product candidates;
- perceived advantages of Trudhesa and any future 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 Trudhesa and any future 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 Trudhesa and any future 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 Trudhesa and any future product candidates;
- relative convenience and ease of administration of Trudhesa and any future product candidates;
- the prevalence and severity of adverse side effects;
- the timing of market introduction of competitive products;
- restrictions on the distribution of Trudhesa and any future product candidates;
- the effectiveness of our sales and marketing efforts;
- unfavorable publicity relating to Trudhesa and any future 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 may not be as large as we expect and, as a result, our product revenues may be lower than expected and our stock price may decline.

Our estimates of the potential market opportunity for Trudhesa 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 addressable migraines, 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 Trudhesa could be smaller than our estimates of our potential market opportunity. If the actual market for Trudhesa 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 for patients and uses of Trudhesa and we anticipate may require similar labeling restrictions for any future product candidates that may be approved by the FDA, including but not limited to contraindications for use in certain populations. For example, upper nasal space drug delivery may not be appropriate for use by patients with certain pre-existing conditions, such as chronic rhinitis with or without nasal polyposis or anatomical nasal obstruction.

If we are unable to maintain and expand commercial distribution capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We may expand our sales and marketing infrastructure for Trudhesa to further penetrate the migraine acute treatment market with Trudhesa or by marketing any future 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 retaining a sales force is expensive and time consuming and challenges could impact the trajectory and performance of a product.

Factors that may inhibit our efforts to commercialize Trudhesa and any future 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 any future product candidates;
- restricted or closed distribution channels that make it difficult to distribute any future 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 any future 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 any future 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 any future product candidates.

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

Manufacturing finished drug products, especially in large quantities, is complex. The commercialization of Trudhesa requires several manufacturing steps and involves complex techniques to assure quality and sufficient quantity, especially as the manufacturing scale increases. Additionally, if any future 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 any future 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 Trudhesa or any future product candidates profitably.

In both domestic and foreign markets, sales of Trudhesa and any future product candidates, if approved, will depend, in part, on the extent to which the costs of any future 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 any approved products profitably. Cost-control initiatives could cause us to decrease the price we might establish for any approved products, 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 historical 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 any future product candidates to the payor. Further, there is significant uncertainty related to third-party payor coverage and reimbursement of newly approved product candidates, including any future 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 future product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, Trudhesa and any future other product candidates. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any future 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 any future 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 any future 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 and development of product candidates which may target the same markets as Trudhesa or any future 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 any of our future 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 Trudhesa we are aware of the several competing efforts. Approved acute treatments for migraine include triptans, gepants (such as ZavzpretTM and Nurtec® both commercialized by Pfizer Inc.), 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 Amneal Pharmaceuticals, Inc., Satsuma Pharmaceuticals, Inc. and Zosano Pharma Corporation, whose product candidates use nasal pumps or other drug delivery technologies.

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 space delivery products that may compete with any of our future 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 any of our future product candidates, the ease with which any of our future 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 any future 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, and any future product candidates our ability to commercialize such 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 would assist in the production, assembly, test, validation, supply, storage and distribution of any future 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 any future 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 any future product candidates, if approved, grow, Trudhesa and any future 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 any future product candidates.

We rely on contract research organization, or CROs and other third parties to assist in managing, monitoring and otherwise carrying out nonclinical and clinical trials for 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 any future 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 any future 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 any future 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, and have historically depended, 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 at their facility of our 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 future product candidates. If our future 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 any future 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 future product candidates, our clinical development may be delayed, our costs may be higher than expected or future 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 future product candidates and commercialization of such 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 future 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 future 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 future 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 STOP 301 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. If we encounter similar or other issues in connection with our commercial manufacturing of Trudhesa, we may face delays and shortages in production of Trudhesa, impacting our ability to fill prescriptions, and may face further scrutiny from the SEC.

Our reliance on third parties also reduces our control over any future 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 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 future 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, if we scale up manufacturing of future 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 any future 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 any future 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 any future 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 any future 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 future 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 future product candidates effectively or create sufficient sales.

If we fail to establish and maintain strategic partnerships related to any future 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 Regulatory Review and Approval of Product Candidates

The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for additional 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 product candidate 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 cGMP at the manufacturing facilities. Further, product candidates must be approved by comparable regulatory authorities in other jurisdictions where we intend to market any future 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 future 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 any future 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 future 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 the product candidate to be safe and effective;
- determines that the product candidate does not have an acceptable benefit-risk profile;
- 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 any future 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 change approval policies or adopt new regulations; or
- may not accept a file for submission due to, among other reasons, the content or formatting of the submission.

We have only obtained FDA approval for Trudhesa to date. This relative lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for any future clinical product candidates. If we experience delays in obtaining approval of any future product candidates, 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 any future 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.

Any future NDA submissions may propose to bridge Listed Drugs, or LDs, for which we have conducted a comparative bioavailability study. The approval of Trudhesa or our prior clinical results for prior 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 the pharmacokinetics or pharmacodynamics of different drugs, 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 it relies 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 any future product candidates, or in 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 future product candidates on a timely basis, or at all.

Any of our future clinical trials may not be conducted as planned or completed on schedule, if at all. For example, in February 2023 we announced a strategic reprioritization that included halting research and development efforts for our product candidate INP105. 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:

- changes in funding priorities that may result in delays or postponements of active clinical trials and development programs;
- delays by us in reaching a consensus with regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required Institutional Review Board 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 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 any future product candidates or the other product candidates in a combination product trial or other materials necessary to conduct clinical trials of any of our future 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 future product candidates.

If we are not able to use the 505(b)(2) regulatory approval pathway for regulatory approval of any of our future 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 future product candidates, and in any case may not be successful.

We intend to seek FDA approval for any future 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 future 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 future 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 before any of our future 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 future 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 future 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 future 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 boxed warning. Moreover, even if future 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.

Our marketed product utilizes, and any future product candidates would utilize, similar drug delivery devices. If a drug delivery device in a future clinical trial 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 prior product candidates utilize similar POD devices, which are designed to deliver the drug into the upper nasal space using a gas propellant. While our prior product candidates have been generally well tolerated in nonclinical studies and 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 any future product candidates utilizing the same or similar POD device, including a suspension or delay of all ongoing development for future product candidates, or our marketed product candidate.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of any future 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 future 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 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 CROs the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any future 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 future product candidates;
- the number of patients required for clinical trials of future 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 future product candidates may be greater than we anticipate;
- the supply or quality of future product candidates or other materials necessary to conduct clinical trials of future 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
- any future 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 space delivery or about any future 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, future business will be substantially harmed.

Our marketed product and any future 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 future 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 only obtained regulatory approval for one product candidate, and it is possible that none of our future product candidates we may seek to develop 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 any future 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 future 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 future 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 future 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 any future 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 future 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. 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.

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 any future 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 procedures 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. 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 future 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 any future product candidates would substantially harm our business, prospects, financial condition and results of operations.

Additionally, planned clinical trials may utilize an "open-label" trial design, as did our STOP 301 trial for Trudhesa. An "open-label" clinical trial is one where both the patient and investigator know that the patient is receiving the investigational product candidate. 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 that patients have received treatment and may interpret the information collected 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 future product candidates in clinical trials when studied in a controlled environment with a double-blind placebo or active control.

Our future 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 any future 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 any future product candidates could have a material adverse effect on the development of any future product candidates and our business as a whole. For example, the most common adverse events in our STOP 301 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 any future 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 future product candidates;
- our clinical trials may be put on hold;
- regulatory authorities may withdraw approvals of future 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 any future product candidates and could substantially increase commercialization costs.

Some of our clinical trials for our prior product candidates have been, and we may in the future conduct clinical trials for future 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 prior 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 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, the European Medicines Agency, or 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 any future 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 any future product candidates in those jurisdictions.

We intend to market Trudhesa and any future 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 guarantee approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not guarantee 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 any future product candidates in any foreign market. If we or any future partner are unable to obtain regulatory approval for any future product candidates in one or more significant foreign jurisdictions, then the commercial opportunity for any future product candidates, as well as our financial condition, will be adversely affected.

Even if we receive regulatory approval for any future product candidates, they will be subject to ongoing regulatory requirements, which may result in significant additional expenses. Additionally, Trudhesa and any future 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 any future product candidates.

Any regulatory approvals that we receive for Trudhesa and any future 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 imposition 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 any future 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 any future 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 any future 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 boxed warnings. If we promote any future 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, 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 any future 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) physician assistants, certain types of advanced practice nurses, and teaching hospitals, including ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;
- 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 any future 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 future 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 future 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 any future 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.

On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals

to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These proposals recently culminated in the enactment of the IRA in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in January 2023 for Medicare Part B and October 2022 for Medicare Part D, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. The full economic impact of the IRA is unknown at this time, but the law's passage may affect the pricing of our products and product candidates. The adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue. We expect pricing pressures will continue globally.

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. 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 any future 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.

Risks Related to Our Intellectual Property

If we are not able to obtain and enforce patent protection for our technologies or any future product candidates, development and commercialization of our technology and any future 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 any future product candidates, our technology such as our proprietary POD nasal drug delivery platform, and methods for treating patients using any future 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. Our patent portfolio as of February 1, 2022 contained 8 U.S. issued patents and 34 patents issued in ex-U.S. jurisdictions including Australia, Brazil, Canada, China, Switzerland, Germany, France, Great Britain, Japan, and Russia and 13 U.S. pending applications as well as 80 patent applications pending in ex-U.S. jurisdictions including Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, New Zealand, Russia, South Africa and one pending international patent application that cover our marketed product candidates, historical 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 any future 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 any future 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 future 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 future 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 any future 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 space product candidates that are the same as or similar to any of our future 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 future 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 any future 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 any future 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 space drug delivery. As the field of upper nasal space 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 licensors' 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 licensors' 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 any future 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 any future 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 any future 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 any future 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 any future 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 any future product candidates, and modifications that we may need to apply to our technology or any future 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 any future

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 space 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 any future 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 any future 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 future 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 future 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 any future 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 any future 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, any future product candidates or the use of any future 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 any future 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 any future product candidates that are held to be infringing. We might, if possible, also be forced to redesign our technology or any future 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 future product candidates.

Trudhesa includes a prior-approved formulation of our active pharmaceutical ingredient and certain of our prior 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 future 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 any future 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 any future 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 any future 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 any future 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 may develop 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 any future 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 be required to expand our operations capabilities in the future, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

While we recently conducted a reduction in force to reprioritize on Trudhesa, we may be required to expand our development, regulatory, manufacturing, marketing and sales capabilities in the future, or contract with third parties to provide these capabilities for us, which could result in growth to the number of our employees and the scope of our operations, particularly in the area of commercialization, manufacturing and clinical strategy. Future growth will impose significant added responsibilities on members of our management. Our future financial performance and our ability to commercialize Trudhesa, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. Any expansion of our operations may lead to significant costs and may

divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans 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 any future product candidates.

We are highly dependent on members of our senior management, including Adrian Adams, our Chairman President and Chief Executive Officer, John Hoekman, Ph.D., Chief Technology and Development Officer and one of our founders, and Leonard S. Paolillo, our Chief Commercial Officer. Although we have entered into employment agreements with our executive officers, 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. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize any future product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key 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. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Further, the reduction in employee and non-employee expenses announced in February 2023 may also make retention of our current personnel both more important and more challenging. This reduction in workforce expenses resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel

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

As a public company, and particularly after we are no longer an emerging growth company, we will continue to incur significant legal, accounting and other expenses on an ongoing basis 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 ongoing efforts. Our management and other personnel 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 and future changes to such 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.

Pursuant to Section 404, we are 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 any future product candidates.

We face an inherent risk of product liability as a result of the commercial sale of Trudhesa and any other approved future product candidate, as well as from clinical testing of any future 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 any future 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 future 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 any future 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 any future 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 any future 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 of March 31, 2023. 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.

The ongoing COVID-19 pandemic, 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 any future product candidates.

The continued presence of 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 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 in the future 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 future resurgences of COVID-19 and treat COVID-19 patients is impeded for an extended period of time, we risk a delay in activating sites and enrolling subjects as previously projected. Any such delays to future clinical trials for any future 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 continued presence of the COVID-19 pandemic, we may in the future 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. A new resurgence of infections and deaths related to COVID-19 could also disrupt certain healthcare and healthcare regulatory systems globally. Such disruptions could continue 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 any future product candidates.

The ongoing COVID-19 pandemic could have an adverse impact on our commercialization efforts for Trudhesa due to future government-imposed quarantines, stay at home orders, travel restrictions, mandated business closures and other public health safety measures in response to rising infections and deaths which may result in limiting our ability to hire additional sales force resources, 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, future 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. These factors could have an adverse impact on our business and our ability to effectively commercialize Trudhesa.

We currently utilize third parties to, among other things, manufacture raw materials and any future 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 any future product candidates are adversely impacted by future restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture any future product candidates for our future clinical trials.

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.

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:

- 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 any future 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;
- receipt of marketing approval for any future product candidates;
- results of nonclinical studies and clinical trials of any future 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 any future 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 any future product candidates, clinical trials, manufacturing process or sales and marketing terms;
- 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 March 31, 2023, 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 ongoing COVID-19 pandemic, 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 any future product candidates."

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.

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 any future product candidates, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of any future 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.

We are not currently in compliance with the NASDAQ Global Market's minimum market value of listed securities requirement of $50 million and the NASDAQ Global Market minimum market value of publicly held shares requirement of $15 million. If our common stock is delisted, the market price and liquidity of our common stock and our ability to raise additional capital would be adversely impacted.

Our common stock is currently listed on the NASDAQ Global Market ("Nasdaq"). Continued listing of a security on Nasdaq is conditioned upon compliance with various continued listing standards. On April 11, 2023, we received a letter from Nasdaq notifying us that the Company did not meet the $15 million minimum market value of publicly held shares required to maintain continued listing as set forth in Nasdaq Marketplace Rule 5450(b)(2)(C) (the "MVPHS Rule") for the 30-business day period ended April 5, 2023, and, as a result, we no longer comply with the MVPHS Rule for continued listing on Nasdaq. Additionally, on April 11, 2023, we received a second notice from Nasdaq stating that, for the for the 30-business day period ended April 5, 2023, we had not met the $50 million minimum market value of listed securities required to maintain continued listing as set forth in Nasdaq Marketplace Rule 5450(b)(2)(A) (the "MVLS Rule" and together with the MVPHS Rule, the "Rules").

As provided in the Nasdaq rules, we have 180 calendar days, or until October 9, 2023, to regain compliance. To regain compliance, the market value of our publicly held shares must be $15 million or more for a minimum of 10 consecutive business days and the market value of our listed securities must close at $50 million or more for a minimum of 10 consecutive business days at any time prior to October 9, 2023.

If the Company has not regained compliance with such applicable Rules prior to October 9, 2023, we will also consider whether to apply to transfer our common stock to the Nasdaq Capital Market. The ability to transfer to the Nasdaq Capital Market would be dependent upon our meeting the applicable listing requirements for that exchange. If we are eligible to, and decide to, transition to the Nasdaq Capital Market, the transition would not impact our obligation to file periodic reports and other reports with the Securities and Exchange Commission under applicable federal securities laws.

If the Company does not transfer its securities to the Nasdaq Capital Market or if the Company is unable to regain compliance with the Rules by October 9, 2023, and the Company receives a delisting determination from Nasdaq, the Company may, at that time, request a hearing to remain on the Nasdaq Stock Market, which request will ordinarily suspend such delisting determination until a decision is issued by Nasdaq subsequent to the hearing. We have not yet determined what other actions we may pursue to regain compliance with the above Nasdaq continued listing requirement, and there can be no assurance that we will be able to regain compliance

with such requirement. Our failure to regain compliance with the minimum bid price requirement under the Nasdaq listing rules may result in the delisting of our common stock.

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

None.

(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	
10.1	Oaktree Letter Agreement dated as of March 22, 2023, between the Registrant and Oaktree Fund Administration, LLC, as administrative agent.	10-K	001-40353	10.14	March 27, 2023	
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 Pharmaceuticals Inc.

Date: May 12, 2023

By: /s/ Adrian Adams

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

Date: May 12, 2023

By: /s/ Michael Kalb

Michael Kalb
Chief Financial Officer
(Principal Financial and Accounting Officer)

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 Pharmaceuticals 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in 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: May 12, 2023

By: /s/ Adrian Adams_____
Adrian Adams
Chairman and 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, Michael Kalb, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Impel Pharmaceuticals 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in 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: May 12, 2023

By: /s/ Michael Kalb_____
Michael Kalb
Chief Financial 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 Pharmaceuticals 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 March 31, 2023 (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: May 12, 2023

By: /s/ Adrian Adams
Adrian Adams
Chairman and 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, Michael Kalb, Chief Financial Officer of Impel Pharmaceuticals 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 March 31, 2023 (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: May 12, 2023

By: /s/ Michael Kalb_____
Michael Kalb
Chief Financial Officer
(Principal Accounting and Financial Officer)