UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2025

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: 001-33221

HERON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**94-2875566**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
100 REGENCY FOREST DRIVE, SUITE 300 **CARY, NC** *(Address of principal executive offices)*	**27518** *(Zip Code)*

Registrant's telephone number, including area code:
(858) 251-4400

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 $0.01 per share	HRTX	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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

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

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

Large accelerated filer	☐	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2025 totaled $235.1 million based on the closing price of $2.07 as reported by The Nasdaq Capital Market. As of February 13, 2026, there were 188,537,136 shares of the Company's common stock ($0.01 par value) outstanding.

Documents Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement related to its 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Such Definitive Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates. Except as expressly incorporated by reference, the registrant's Definitive Proxy Statement shall not be deemed to be part of this report.

TABLE OF CONTENTS

PART I

Item 1.	Business	4
Item 1A.	Risk Factors	18
Item 1B.	Unresolved Staff Comments	56
Item 1C.	Cybersecurity	56
Item 2.	Properties	56
Item 3.	Legal Proceedings	57
Item 4.	Mine Safety Disclosures	59

PART II

Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	60
Item 6.	[Reserved]	61
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	62
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	70
Item 8.	Financial Statements and Supplementary Data	70
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	102
Item 9A.	Controls and Procedures	102
Item 9B.	Other Information	103
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	103

PART III

Item 10.	Directors, Executive Officers and Corporate Governance	104
Item 11.	Executive Compensation	104
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	104
Item 13.	Certain Relationships and Related Transactions, and Director Independence	104
Item 14.	Principal Accountant Fees and Services	104

PART IV

Item 15.	Exhibit and Financial Statement Schedules	105
	Exhibit Index	106
Item 16.	Form 10-K Summary	109
	Signatures	110

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, you can identify forward-looking statements by the use of the words "anticipate," "assume," "believe," "could," "estimate," "expect," "intend," "may," "might," "project," "should," "will," "would," and other expressions that predict or indicate future events and trends and which do not relate to historical matters. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business and commercialization strategy, products and product candidates, research pipeline, ongoing and planned preclinical studies and clinical trials, regulatory submissions and approvals, addressable patient population, research and development expenses, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control. These risks, uncertainties and other factors may cause our actual results, performance or achievements to be materially different from our anticipated future results, performance or achievements expressed or implied by the forward-looking statements.

Forward-looking statements include, but are not limited to, statements including:

- our ability to successfully commercialize, market and achieve market acceptance of ZYNRELEF® (bupivacaine and meloxicam) extended-release solution ("ZYNRELEF"), APONVIE® (aprepitant) injectable emulsion ("APONVIE"), CINVANTI® (aprepitant) injectable emulsion ("CINVANTI"), and SUSTOL® (granisetron) extended-release injection ("SUSTOL" and together with ZYNRELEF, APONVIE and CINVANTI, our "Products") in the United States ("U.S.") , and our positioning relative to products that now or in the future compete with our Products or product candidates;

- our estimates regarding the potential market opportunities for our Products and any product candidates, if approved.;

- our ability to establish and maintain successful commercial arrangements, including our co-promotion agreement with Crosslink Network, LLC ("Crosslink Network");

- the realization of anticipated benefits from our co-promotion agreement with Crosslink Network;

- the timing and outcome of our pending patent litigations;

- whether we are required to write-off any additional inventory in the future;

- our ability to establish satisfactory pricing and obtain adequate reimbursement from government and third-party payors of our Products and product candidates that receive regulatory approvals;

- whether clinical trials of our Products and product candidates are indicative of the results in future clinical trials;

- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials, and our ability to submit for and obtain regulatory approval for product candidates in our anticipated timing, or at all;

- the clinical utility of our Products and product candidates and their potential advantages compared to other treatments;

- our competitors' activities, including decisions as to the timing of competing product launches, generic entrants, pricing and discounting;

- the safety and efficacy results of our clinical trials and other required studies for expansion of the indications for our Products and approval of any product candidates and the data to support such clinical trials, potential regulatory approval or further development of any of our Products or product candidates;

- our ability to meet the postmarketing study requirements within the mandated timelines of the U.S. Food and Drug Administration ("FDA") and to obtain favorable results and comply with standard postmarketing requirements, including U.S. federal advertising and promotion laws, federal and state anti-fraud and abuse laws, healthcare information privacy and security laws, safety information, safety surveillance and disclosure of payments or other transfers of value to healthcare professionals and entities for Products or any of our product candidates;

- our ability to successfully develop and achieve regulatory approval for any product candidates utilizing our proprietary Biochronomer® drug delivery technology ("Biochronomer Technology");

- our ability to establish key collaborations and vendor relationships for our Products and any product candidates;

- our ability to successfully develop and commercialize any technology that we may in-license or products we may acquire;

- our ability to establish and maintain arrangements for the manufacture of our Products and product candidates and the ability and sufficiency of our current manufacturing third-party partners to produce clinical and commercial quantities of our Products and product candidates without delays, supply constraints or changes in the regulatory or geopolitical environment;

- the failure to renew, or the revocation of, any license or other required permits;

- our ability to scale manufacturing capacity appropriately to meet demand;

- unanticipated delays due to manufacturing difficulties, supply constraints or changes in the regulatory environment, including as a result of geopolitical uncertainty;

- our ability to successfully operate in non-U.S. jurisdictions in which we may choose to do business, including compliance with applicable regulatory requirements and laws;

- our ability to obtain and enforce intellectual property rights to protect our Products, our product candidates, our Biochronomer Technology and our other technology;

- our ability to successfully defend ourselves against pending or threatened litigation or investigations, including unforeseen third-party infringement claims involving our Products and product candidates;

- our estimates regarding our capital requirements;

- our inability to achieve, or delay in achieving, profitability;

- the impacts of global economic and political developments on our business and the financial market, including the impact of geopolitical conflicts and acts of war, terrorism and civil disorder, global pandemics and other public health emergencies, tariffs and other trade protection measures, changes to interest rates and inflationary pressure, natural and man-made disasters, and other sources of volatility, which could result in economic slowdowns or recessions and market disruptions and adversely affect our financial condition, results of operations and cash flows;

- the impact of evolving legal and regulatory requirements and interpretations thereof, including legislative or executive actions, policy changes in governmental agencies and judicial decisions overturning or establishing new precedents;

- changes in the industry we operate;

- our ability to retain, attract and hire key personnel;

- our estimates regarding our capital requirements;

- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities;

- the cost and availability of capital and any restrictions imposed by lenders or creditors; and

- the volatility and unpredictability of the stock market, credit market conditions and impact on the value of our common stock and our ability to access capital markets.

You should refer to the "Risk Factors" in this Annual Report on Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements were based on information, plans and estimates as of the date of this Annual Report on Form 10-K, and while we may elect to update these forward-looking statements in our future filings under the Exchange Act, we assume no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes, except as required by law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I

In this Annual Report on Form 10-K, all references to "Heron," the "Company," "we," "us," "our" and similar terms refer to Heron Therapeutics, Inc. and its wholly-owned subsidiary, Heron Therapeutics B.V. Heron Therapeutics®, the Heron logo, ZYNRELEF, APONVIE, CINVANTI, SUSTOL and Biochronomer are our trademarks. All other trademarks appearing or incorporated by reference into this Annual Report on Form 10-K are the property of their respective owners.

ITEM 1. BUSINESS.

Overview

We are a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard of care for acute care and oncology patients.

Acute Care Product Portfolio

ZYNRELEF

ZYNRELEF is a dual-acting local anesthetic that delivers a fixed-dose combination of the local anesthetic bupivacaine and a low dose of the nonsteroidal anti-inflammatory drug meloxicam. ZYNRELEF is the first and only modified-release local anesthetic to be classified by the FDA as an extended-release product because ZYNRELEF demonstrated in Phase 3 studies significantly reduced pain and significantly increased proportion of patients requiring no opioids through the first 72 hours following surgery compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control.

ZYNRELEF was initially approved by the FDA in May 2021, and we commenced commercial sales in the U.S. in July 2021. In each of December 2021 and January 2024, the FDA approved an expansion of ZYNRELEF's indication. ZYNRELEF is approved for use in adults for postsurgical analgesia for up to 72 hours after soft tissue and orthopedic surgical procedures including foot and ankle, and other orthopedic surgical procedures in which direct exposure to articular cartilage is avoided. In September 2024, the FDA approved the prior approval supplement ("PAS") application for ZYNRELEF Vial Access Needle ("VAN"), which is replacing the current vented vial spike.

Through March 31, 2025, ZYNRELEF was reimbursed outside of the surgical bundle payment in the Hospital Outpatient Department ("HOPD") setting of care through pass-through status granted by the Centers for Medicare and Medicaid Services ("CMS").

Effective April 1, 2025, ZYNRELEF is reimbursed through inclusion in the Non-Opioids Prevent Addiction in the Nation ("NOPAIN") Act, which directs CMS to provide separate Medicare reimbursement for non-opioid treatments that are used to manage pain during surgeries conducted in hospital outpatient departments or in ambulatory surgical centers. To qualify, the non-opioid treatment must demonstrate the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. The hospital outpatient prospective payment system and ambulatory surgical center proposed rule for calendar year 2025 includes ZYNRELEF as a qualifying non-opioid requiring CMS to provide separate Medicare reimbursement in both the hospital outpatient department and ambulatory surgical center settings through December 31, 2027.

Effective October 1, 2025, CMS has approved a new permanent Healthcare Common Procedure Coding System J-code for ZYNRELEF. ZYNRELEF will continue to qualify under the Non-Opioid Policy for Pain Relief with the J-code and will be reimbursed outside the surgical supply package for Medicare, aligning with the policy goals to remove financial barriers to qualifying non-opioid pain management options.

APONVIE

APONVIE is the first and only intravenous formulation of aprepitant, a substance P/neurokinin-1 ("NK1") receptor antagonist indicated for postoperative nausea and vomiting ("PONV") in adults. Delivered via a single 30-second intravenous ("IV") injection, APONVIE has demonstrated rapid achievement of therapeutic drug levels ideally suited for the surgical setting.

APONVIE was approved by the FDA in September 2022 and became commercially available in the U.S. in March 2023. APONVIE is indicated for the prevention of PONV in adults. CMS granted pass-through payment status for APONVIE, effective April 1, 2023.

In 2025, APONVIE was included in the Fifth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting as published in Anesthesia and Analgesia.

Oncology Care Product Portfolio

CINVANTI

CINVANTI is an IV formulation of aprepitant, a substance NK1 receptor antagonist. CINVANTI is the first IV formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is a single-agent NK1 receptor antagonist to significantly reduce nausea and vomiting in both the acute phase (0–24 hours after chemotherapy) and the delayed phase (24–120 hours after chemotherapy). CINVANTI is the first and only IV formulation of an NK1 receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with Highly Emetogenic Cancer ("HEC") and nausea and vomiting associated with Moderately Emetogenic Cancer ("MEC") that is free of synthetic surfactants, including polysorbate 80.

CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of HEC including high-dose cisplatin as a single-dose regimen, delayed nausea and vomiting associated with initial and repeat courses of MEC as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen.

NK1 receptor antagonists are typically used in combination with 5-hydroxytryptamine ("5-HT3") receptor antagonists. The only other injectable NK1 receptor antagonist currently approved in the U.S. for both acute and delayed chemotherapy induced nausea and vomiting ("CINV"), EMEND® IV (fosaprepitant), contains polysorbate 80, a synthetic surfactant, which has been linked to hypersensitivity reactions, including anaphylaxis, and infusion site reactions. The CINVANTI formulation does not contain polysorbate 80 or any other synthetic surfactant. Our CINVANTI data has demonstrated the bioequivalence of CINVANTI to EMEND IV, supporting its efficacy for the prevention of both acute and delayed nausea and vomiting associated with HEC and nausea and vomiting associated with MEC. Results also showed CINVANTI was better tolerated in healthy volunteers than EMEND IV, with significantly fewer adverse events reported with CINVANTI.

CINVANTI was approved by the FDA in November 2017, and we commenced commercial sales in the U.S. in January 2018.

SUSTOL

SUSTOL is the first extended-release 5-HT3 receptor antagonist approved for the prevention of acute and delayed nausea and vomiting associated with both MEC and anthracycline and cyclophosphamide ("AC") combination chemotherapy regimens. A standard of care in the treatment of breast cancer and other cancer types, AC regimens are among the most commonly prescribed HEC regimens, as defined by both the National Comprehensive Cancer Network ("NCCN") and the American Society of Clinical Oncology ("ASCO").

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of MEC or AC combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-HT3 receptor antagonist that utilizes our Biochronomer Technology to maintain therapeutic levels of granisetron for ≥5 days. The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical studies that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (0–24 hours following chemotherapy) and the delayed phase (24–120 hours following chemotherapy).

SUSTOL was approved by the FDA in August 2016, and we commenced commercial sales in the U.S. in October 2016.

Biochronomer Technology

Our proprietary Biochronomer Technology is designed to deliver therapeutic levels of a wide range of otherwise short-acting pharmacological agents over a period from days to weeks with a single administration. Our Biochronomer Technology consists of polymers that have been the subject of comprehensive animal and human toxicology studies that have shown evidence of the safety of the polymer. When administered, the polymers undergo controlled hydrolysis, resulting in a controlled, sustained release of the pharmacological agent encapsulated within the Biochronomer-based composition. Furthermore, our Biochronomer Technology is designed to permit more than one pharmacological agent to be incorporated, such that multimodal therapy can be delivered with a single administration.

Sales and Marketing

Our U.S.-based sales and marketing team consists of 78 employees as of December 31, 2025. The sales and marketing infrastructure includes a targeted, acute care and oncology sales force to establish relationships with a focused group of surgeons, oncologists, nurses and pharmacists. Additionally, the commercial team manages relationships with key accounts, such as managed care organizations, group purchasing organizations, hospital systems, oncology group networks, payors and government accounts. The sales force is supported by sales management, internal sales support, an internal marketing group and distribution support.

In January 2024, we entered into a co-promotion agreement with Crosslink Network to expand the sales network supporting ZYNRELEF. Crosslink Network is the lead partner in the U.S. for ZYNRELEF promotion for orthopedic indications.

Customers

Our Products are distributed in the U.S. through a limited number of specialty distributors and full line wholesalers that resell to healthcare providers and hospitals, the end users of our Products.

Competition

The biotechnology and pharmaceutical industries are extremely competitive. Our potential competitors are many in number and include major and mid-sized pharmaceutical and biotechnology companies. Many of our potential competitors have significantly more financial, technical and other resources than we do, which may give them a competitive advantage. In addition, they may have substantially more experience in effecting strategic combinations, in-licensing technology, developing drugs, obtaining regulatory approvals and manufacturing and marketing products. We cannot give any assurances that we can compete effectively with these other biotechnology and pharmaceutical companies. Our Products compete in highly competitive markets. Our potential competitors in these markets may succeed in developing products that could render our Products obsolete or noncompetitive.

ZYNRELEF competes in the postoperative pain management market with MARCAINETM (bupivacaine hydrochloride injection, solution, marketed by Pfizer Inc.) and generic forms of bupivacaine; NAROPIN® (ropivacaine, marketed by Fresenius Kabi USA, LLC) and generic forms of ropivacaine; EXPAREL® (bupivacaine liposome injectable suspension, marketed by Pacira BioSciences, Inc.); XARACOLL® (bupivacaine HCl implant, marketed by Innocoll Pharmaceuticals Limited); POSIMIR® (owned by Durect Corporation and to be marketed in the U.S. by Innocoll Pharmaceuticals Limited); ANJESO® (meloxicam injection, marketed by Baudax Bio, Inc.); OFIRMEV® (acetaminophen injection, marketed by Mallinckrodt Pharmaceuticals); SEGLENTIS® (celecoxib and tramadol hydrochloride, marketed by Kowa Pharmaceuticals America, Inc. in the U.S.); generic forms of IV acetaminophen; and potentially other products in development for postoperative pain management that reach the U.S. market.

APONVIE competes in the PONV prevention market with generic ondansetron, the current standard of care, generic oral aprepitant, and BARHEMSYS® (amisulpride, marketed by Eagle Pharmaceuticals, Inc.); TAK-951 (a peptide agonist under development (PH2) by Takeda Pharmaceutical Company Limited for PONV and not approved anywhere globally for any use); and potentially other products in development for PONV prevention that reach the market.

CINVANTI faces significant competition. NK1 receptor antagonists are administered for the prevention of CINV, in combination with 5-HT3 receptor antagonists, to augment the therapeutic effect of the 5-HT3 receptor antagonist. Currently available NK1receptor antagonists include: generic versions of EMEND® IV (fosaprepitant); EMEND® IV (fosaprepitant, marketed by Merck & Co., Inc.); EMEND® (aprepitant, marketed by Merck & Co., Inc.); AKYNZEO®(palonosetron, a 5-HT3 receptor antagonist, combined with netupitant, an NK1 receptor antagonist, marketed by Helsinn Therapeutics (U.S.), Inc.); VARUBI® (rolapitant, marketed by TerSera Therapeutics LLC), FOCINVEZTM (fosaprepitant injection, marketed by Amneal Pharmaceuticals, LLC) and other products that include an NK1 receptor antagonist that reach the market for the prevention of CINV.

SUSTOL also faces significant competition. Currently available 5-HT3 receptor antagonists include: AKYNZEO® (palonosetron, a 5-HT3 receptor antagonist, combined with netupitant, an NK1 receptor antagonist, marketed by Helsinn Therapeutics (U.S.), Inc.); SANCUSO® (granisetron transdermal patch, marketed by Cumberland Pharmaceuticals Inc.); and generic products including ondansetron (formerly marketed by GlaxoSmithKline plc as ZOFRAN), granisetron (formerly marketed by Hoffman-La Roche, Inc. as KYTRIL) and palonosetron (formerly marketed by Eisai in conjunction with Helsinn Healthcare S.A. as ALOXI) and Posfrea (Palonosetron Injection, marketed by AVYXA). Currently, palonosetron is the only 5-HT3receptor antagonist other than SUSTOL that is approved for the prevention of delayed CINV associated with MEC regimens. SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of MEC or AC combination chemotherapy regimens, which is considered to be a HEC regimen by the NCCN and ASCO. No other 5-HT3 receptor antagonist is specifically approved for the prevention of delayed CINV associated with a HEC regimen.

Manufacturing and Clinical Supplies

We do not own or operate manufacturing facilities for the production of commercial or clinical quantities of our Products. We currently rely on a small number of third-party manufacturers to produce compounds used in our product development and commercial activities and expect to continue to do so to meet the preclinical and clinical requirements of our Products and potential products and for all of our commercial needs. We currently have long-term manufacturing and processing agreements with certain third-party manufacturers. These agreements require that all third-party contract manufacturers and processors produce active pharmaceutical ingredients, excipients and finished products in accordance with the FDA’s current Good Manufacturing Practices ("cGMP") and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our Products and our Biochronomer Technology.

Some of the critical materials and components used in manufacturing our Products are sourced from single suppliers. An interruption in the supply of a key material could significantly delay or increase our expenses for commercialization or development of our Products. Specialized materials must often be manufactured for the first time for use in drug delivery technologies, or materials may be used in the technologies in a manner that is different from their customary commercial uses. The quality of materials can be critical to the performance of a drug delivery technology, so a reliable source that provides a consistent supply of materials is important. Materials or components needed for our drug delivery technologies may be difficult to obtain on commercially reasonable terms, particularly when relatively small quantities are required or if the materials traditionally have not been used in pharmaceutical products.

Intellectual Property

Our success will depend in large part on our ability to:

- obtain and maintain international and domestic patents and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;
- prosecute and defend our patents;
- preserve our trade secrets; and
- operate without infringing the patents and proprietary rights of other parties.

We intend to continue to seek appropriate patent protection for the product candidates in our research and development programs and their uses by filing patent applications in the U.S. and other selected countries. We intend for these patent applications to cover, where possible, claims for composition of matter, medical uses, processes for preparation and formulations.

Our policy is to actively seek patent protection in the U.S. and to pursue equivalent patent claims in selected foreign countries, thereby seeking patent coverage for novel technologies and compositions of matter that may be commercially important to the development of our business. Granted patents include claims covering the product composition, methods of use and methods of preparation. Our existing patents may not cover future products, additional patents may not be issued and current patents, or patents issued in the future, may not provide meaningful protection or prove to be of commercial benefit.

We have filed a number of U.S. patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. As of December 31, 2025, we had a total of 33 issued U.S. patents and an additional 107 issued (or registered) foreign patents. The patent on the bioerodible technologies expires in April 2026.

CINVANTI is covered by 13 patents issued in the U.S. and by five patents issued (or registered) in foreign countries including Korea and Japan. U.S. patents covering CINVANTI have expiration dates ranging from September 2035 to February 2036. Foreign patents covering CINVANTI have expiration dates ranging from September 2035 to February 2036.

ZYNRELEF is protected by 17 patents issued in the U.S. and by 100 patents issued (or registered) in foreign countries including Albania, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Mexico, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan, Turkey and the United Kingdom. U.S. patents covering ZYNRELEF have expiration dates ranging from March 2034 to April 2035. Foreign patents covering ZYNRELEF have expiration dates ranging from November 2033 to November 2036.

APONVIE is covered by 14 patents issued in the U.S. and by five patents issued (or registered) in foreign countries including Korea and Japan. U.S. patents covering APONVIE have expiration dates ranging from September 2035 to February 2036. Foreign patents covering APONVIE have expiration dates ranging from September 2035 to February 2036.

HTX-034 is protected by 14 patents issued in the U.S. and by 101 patents issued (or registered) in foreign countries including Albania, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Mexico, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan, Turkey and the United Kingdom. U.S. patents covering HTX-034 have expiration dates ranging from March 2034 to April 2035. Foreign patents covering HTX-034 have expiration dates ranging from November 2033 to November 2036.

Although we believe that our rights under patent applications we own provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes, and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. Any patents or patent rights that we obtain may be circumvented, challenged or invalidated by our competitors.

We also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position. We seek protection of these trade secrets, proprietary know-how and any continuing innovation, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide meaningful protection for, or adequate remedies to protect, our technology in the event of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

Government Regulation

Pharmaceutical Regulation

Pharmaceutical products that we market in the U.S. are subject to extensive government regulation. Likewise, if we receive approvals to market and distribute any such products abroad, they would also be subject to extensive foreign government regulation. Compliance with these regulations has not had a material effect on our capital expenditures, earnings, or competitive position to date, but new regulations or amendments to existing regulations to make them more stringent could have such an effect in the future. We cannot estimate the expenses we may incur to comply with potential new laws or changes to existing laws, or the other potential effects these laws may have on our business.

In the U.S., the FDA regulates pharmaceutical products. FDA regulations govern the testing, research and development activities, manufacturing, quality, storage, advertising, promotion, labeling, sale and distribution of pharmaceutical products. Accordingly, there is a rigorous process for the approval of new drugs and ongoing oversight of marketed products. We are also subject to foreign regulatory requirements governing clinical trials and drug products if products are tested or marketed abroad. The approval process outside the U.S. varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

Regulation in the U.S.

The FDA testing and approval process requires substantial time, effort and money. The FDA approval process for new drugs includes, without limitation:

- preclinical studies;
- submission in the U.S. of an Investigational New Drug application ("IND"), for clinical trials conducted in the U.S.;
- adequate and well-controlled human clinical trials to establish safety and efficacy of the product;
- submission and review of a New Drug Application ("NDA") in the U.S.; and
- inspection of the facilities used in the manufacturing of the drug to assess compliance with the FDA’s current cGMP regulations.

The FDA monitors the progress of trials conducted in the U.S. under an IND and may, at its discretion, re-evaluate, alter, suspend or terminate testing based on the data accumulated to that point and the FDA's risk/benefit assessment with regard to the patients enrolled in the trial. The FDA may also place a hold on one or more clinical trials conducted under an IND for a drug if it deems warranted. Furthermore, even after regulatory approval of an NDA is obtained, under certain circumstances, such as later discovery of previously unknown problems, the FDA can withdraw approval or subject the drug to additional restrictions.

Preclinical Testing

Preclinical studies include laboratory evaluation of the product and animal studies to assess the potential safety and effectiveness of the product. Most of these studies must be performed according to Good Laboratory Practices, a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results.

An IND is the request for authorization from the FDA to administer an investigational new drug product to humans. The IND includes information regarding the preclinical studies, the investigational product's chemistry and manufacturing, supporting data and literature and the investigational plan and protocol(s). Clinical trials may begin 30 days after an IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, an IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. An IND must become effective before human clinical trials begin. We have filed INDs in the U.S. and Clinical Trial Applications ("CTAs") in the EU, and we may file additional INDs and CTAs in the future. We cannot assure that submission of any additional INDs or CTAs for any of our Products will result in authorization to commence clinical trials.

Clinical Trials

Clinical trials involve the administration of the product candidate that is the subject of the trial to volunteers or patients under the supervision of a qualified principal investigator and in accordance with a clinical trial protocol, which sets forth details, such as the study objectives, enrollment criteria and the safety and effectiveness criteria to be evaluated. Each clinical trial must be reviewed and approved at each institution at which the study will be conducted by an independent Institutional Review Board in the U.S., referred to as an Ethics Committee in the EU and other markets or Research Ethics Board in Canada. The Institutional Review Board, Ethics Committee or Research Ethics Board (hereafter collectively referred to as "IRB") will consider, among other things, ethical factors, safety of human subjects and the possible liability of the institution arising from the conduct of the proposed clinical trial. In addition, clinical trials in the U.S. and other regions must be performed according to current Good Clinical Practices, which are enumerated in FDA regulations and guidance documents. Some studies include oversight by an independent group of experts, known as a data safety monitoring board, which authorizes whether a study may move forward based on certain data from the study and may stop the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds.

The FDA or other regulatory authorities may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it or they believe that the clinical trial is not being conducted in accordance with regulatory requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or it may impose other conditions.

Clinical trials typically are conducted in sequential phases: Phases 1, 2, 3 and 4. The phases may overlap. The FDA may require that we suspend clinical trials at any time on various grounds, including if the FDA makes a finding that the subjects participating in the trial are being exposed to an unacceptable health risk.

In Phase 1 clinical trials, the investigational product is usually tested on a small number of healthy volunteers to determine safety, any adverse effects, proper dosage, absorption, metabolism, distribution, excretion and other drug effects. Follow-on Phase 1b clinical trials may also evaluate efficacy with respect to trial participants.

In Phase 2 clinical trials, the investigational product is usually tested on a limited number of patients (generally up to several hundred) to preliminarily evaluate the efficacy of the drug for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning Phase 3 clinical trials.

In Phase 3 clinical trials, the investigational product is administered to an expanded patient population to confirm proof of concept and efficacy claims, provide evidence of clinical efficacy and to further test for safety, generally at multiple clinical sites.

In Phase 4 clinical trials or other post-approval commitments, additional studies and patient follow-up are conducted to gain experience from the treatment of patients in the intended therapeutic indication. The FDA and other regulatory authorities may require a commitment to conduct post-approval Phase 4 studies as a condition of approval. Additional studies and follow-up may be conducted to document a clinical benefit where drugs are approved under accelerated approval regulations and based on surrogate endpoints. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. In the U.S., failure to timely conduct Phase 4 clinical trials and follow-up could result in withdrawal of approval for products approved under accelerated approval regulations.

Clinical Data Review and Approval in the U.S.

The data from the clinical trials, together with preclinical data and other supporting information that establishes a drug candidate's safety, are submitted to the FDA in the form of an NDA, or sNDA (for approval of a new indication if the product candidate is already approved for another indication). Under applicable laws and FDA regulations, the FDA reviews the NDA within 60 days of receipt of the NDA submission to determine whether the application will be accepted for filing based on the FDA's threshold determination that the NDA is sufficiently complete to permit substantive review. If deemed complete, the FDA will "file" the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable.

The FDA has established internal substantive review goals of 10 months for most NDAs. The FDA has various programs, including Breakthrough Therapy, Fast Track and Priority Review, which are intended to expedite or simplify the process for reviewing drug candidates, and/or provide for approval based on surrogate endpoints. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification or that the period for FDA review or approval will not be shortened. Generally, drug candidates that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious diseases and fill an unmet medical need. The request may be made at the time of IND submission and generally no later than the pre-NDA meeting. The FDA will respond within 60 calendar days of receipt of the request. Priority Review designation, which is requested at the time of an NDA submission, is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists, an initial review within 6 months as compared to a standard review time of 10 months. Although Fast Track and Priority Review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for Priority Review. Accelerated approval provides an expedited approval of drugs that treat serious diseases and that fill an unmet medical need based on a surrogate endpoint. The FDA, however, is not legally required to complete its review within these periods, and these performance goals may change over time.

If the FDA approves the NDA, it will issue an approval letter authorizing the commercial marketing of the drug with prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS"), to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. In many cases, the outcome of the review, even if generally favorable, is not an actual approval, but a "complete response" that generally outlines the deficiencies in the submission, which may require substantial additional testing or information before the FDA will reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and requires the expenditure of substantial financial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the process. Accordingly, the actual time and expense required to bring a product to market may vary substantially. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Success in early-stage clinical trials does not ensure success in later-stage clinical trials. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages, or have conditions placed on it that restrict the commercial applications, advertising, promotion or distribution of these products.

Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the safety or effectiveness of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these postmarketing programs. The FDA may also request or require additional Phase 4 clinical trials after a product is approved. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA's voluntary adverse drug reaction reporting system. Any products manufactured or distributed by us pursuant to FDA approvals would be subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements on us and our third-party manufacturers.

In addition, both before and after approval is sought, we are required to comply with a number of FDA requirements. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain limitations and other requirements concerning advertising and promotion for our products. In addition, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with continuing cGMP. In addition, discovery of problems, such as safety problems, may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

The FDA closely regulates the marketing and promotion of drugs. Approval may be subject to postmarketing surveillance and other recordkeeping and reporting obligations and involve ongoing requirements. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Clinical Trial Conduct and Product Approval Regulation in Non-U.S. Jurisdictions

In addition to regulations in the U.S., we may be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. For example, our clinical trials conducted in the EU must be done under an Investigational Medicinal Product Dossier, and the oversight of an Ethics Committee. If we market our products in foreign countries, we also will be subject to foreign regulatory requirements governing marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for such approvals may differ substantially from that required for FDA approval. There is no assurance that any future FDA approval of any of our product candidates will result in similar foreign approvals or vice versa. The process for clinical trials in other jurisdictions are similar, and trials are heavily scrutinized by the designated Ethics Committee.

Section 505(b)(2) Applications

Some of our product candidates may be eligible for submission of applications for approval under the FDA's Section 505(b)(2) approval process, which provides an alternate path to FDA approval for new or improved

formulations or new uses of previously approved products. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and allows approval of NDAs that rely, at least in part, on studies that were not conducted by or for the applicant and to which the applicant has not obtained a right of reference. Such studies can be provided by published literature, or the FDA can rely on previous findings of safety and efficacy for a previously approved drug. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. Section 505(b)(2) applications may be submitted for drug products that represent a modification (e.g., a new indication or new dosage form) of an eligible approved drug. In such cases, the additional information in 505(b)(2) applications necessary to support the change from the previously approved drug is frequently provided by new studies submitted by the applicant. Because a Section 505(b)(2) application relies in part on previous studies or previous FDA findings of safety and effectiveness, preparing 505(b)(2) applications is generally less costly and time-consuming than preparing an NDA based entirely on new data and information from a full set of clinical trials. The FDA may approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The law governing Section 505(b)(2) or FDA's current policies may change in such a way as to adversely affect our applications for approval that seek to utilize the Section 505(b)(2) approach. Such changes could result in additional costs associated with additional studies or clinical trials and delays.

The FDA provides that reviews and/or approvals of applications submitted under Section 505(b)(2) will be delayed in various circumstances. For example, the holder of the NDA for the listed drug may be entitled to a period of market exclusivity during which the FDA will not approve, and may not even review, a Section 505(b)(2) application from other sponsors. If the listed drug is claimed by one or more patents that the NDA holder has listed with the FDA, the Section 505(b)(2) applicant must submit a certification with respect to each such patent. If the 505(b)(2) applicant certifies that a listed patent is invalid, unenforceable or not infringed by the product that is the subject of the Section 505(b)(2) application, it must notify the patent holder and the NDA holder. If, within 45 days of providing this notice, the NDA holder sues the 505(b)(2) applicant for patent infringement, the FDA will not approve the Section 505(b)(2) application until the earlier of a court decision favorable to the Section 505(b)(2) applicant or the expiration of 30 months. The regulations governing marketing exclusivity and patent protection are complex, and it is often unclear how they will be applied in particular circumstances.

Drug Enforcement Agency Regulation

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Some of these hazardous materials are considered to be controlled substances and subject to regulation by the U.S. Drug Enforcement Agency ("DEA"). Controlled substances are those drugs that appear on one of 5 schedules promulgated and administered by the DEA under the Controlled Substances Act ("CSA"). The CSA governs, among other things, the distribution, recordkeeping, handling, security and disposal of controlled substances. We must be registered by the DEA in order to engage in these activities, and we are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of the DEA registration, injunctions or civil or criminal penalties.

Third-party Payor Coverage and Reimbursement

Commercial success of our Products will depend, in part, on the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Government payor programs, including Medicare and Medicaid, private healthcare insurance companies and managed care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The U.S. Congress and state legislatures, from time to time, propose and adopt initiatives aimed at cost containment. Ongoing federal and state government initiatives directed at lowering the total cost of healthcare will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems. Examples of how limits on drug coverage and reimbursement in the U.S. may cause reduced payments for drugs in the future include:

- changing Medicare reimbursement methodologies;

- fluctuating decisions on which drugs to include in formularies;
- revising drug rebate calculations under the Medicaid program or requiring that new or additional rebates be provided to Medicare, Medicaid and other federal or state healthcare programs; and
- reforming drug importation laws.

Some third-party payors also require pre-approval of coverage for new drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our current and future products and to operate profitably.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis. In many foreign markets, including markets in which we hope to sell our Products, the pricing of prescription pharmaceuticals is subject to government pricing control. In these markets, once marketing approval is received, pricing negotiations could take significant additional time. As in the U.S., the lack of satisfactory reimbursement or inadequate government pricing of any of our Products would limit widespread use and lower potential Product revenues.

Anti-kickback, Fraud and Abuse and False Claims Regulation

We are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of our Products. Arrangements with third-party payors and customers may expose us to 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.

Regulations under applicable federal and state healthcare laws and regulations include the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral or purchase of any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced-price items and services. Many states have similar laws that apply to their state healthcare programs as well as private payors. In addition, the False Claims Act ("FCA") imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal healthcare program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the United States Department of Justice ("DOJ") or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Various healthcare reform legislation have strengthened many of these laws. For example, the Patient Protection and Affordable Care Act ("PPACA"), among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes to clarify that a person or entity does not need to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides 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 false claims statutes.

The continuing interpretation and application of these laws could have a material adverse impact on our business and our ability to compete in a highly competitive market.

Federal and State Sunshine Laws

We must comply with federal and state "sunshine" laws, now known as Open Payments that require transparency regarding financial arrangements with healthcare providers. This would include the reporting and disclosure requirements imposed by the PPACA on drug manufacturers regarding any "payment or transfer of value" made or distributed to physicians and teaching hospitals. Failure to submit required information can result in civil monetary penalties. A number of states have laws that require the implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require pharmaceutical companies to track and report payments, gifts and other benefits provided to physicians and other healthcare professionals and entities.

Foreign Corrupt Practices Act

We are subject to the Foreign Corrupt Practices Act of 1997 ("FCPA"). The FCPA and other similar anti-bribery laws in other jurisdictions, such as the U.K. Bribery Act, generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. A determination that our operations or activities are not, or were not, in compliance with U.S. or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence. We have a policy against using Company funds for political purposes, and we incurred no costs in 2025, 2024 or 2023 associated with legal or regulatory fines or settlements associated with violations of bribery, corruption or anti-competitive standards.

Patient Privacy and Data Security

We are required to comply, as applicable, with numerous federal and state laws, including state security breach notification laws, state health and personal information privacy laws and federal and state consumer protection laws, and to govern the collection, use and disclosure of personal information. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act of 2020 (collectively, the "CCPA"), gives California residents expanded rights to access and request deletion of their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. Other states have also passed comprehensive data privacy and security laws, and similar laws are being considered in several other states, as well as the federal and local levels. Other countries also have developed, or are developing, laws governing the collection, use and transmission of personal information, such as the General Data Protection Regulation in the European Union and its United Kingdom equivalent thereof (collectively, the "GDPR") and the Personal Information Protection and Electronic Documents Act ("PIPEDA") in Canada. In addition, most healthcare providers who utilize our Products or who may utilize other products we may sell in the future are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations (collectively, "HIPAA"). We are not a HIPAA covered entity, do not intend to become one, and we do not operate as a business associate to any covered entities. Therefore, these privacy and security requirements do not apply to us. However, we could be subject to civil and criminal penalties if we knowingly obtain individually identifiable or protected health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including through affecting our customers. These laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation, and potentially fines and penalties.

In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Environmental, Health and Safety Laws

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations. Further, in the future, we may open manufacturing facilities that would likely be subject to environmental and health and safety authorities in the relevant jurisdictions. These authorities typically administer laws which regulate, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. Violations of these laws could subject us to strict liability, fines or liability to third parties.

Other Laws

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the SEC and the regulations of The Nasdaq Capital Market, on which our shares are traded. We are also subject to various laws, regulations and recommendations relating to safe working conditions, laboratory practices and the experimental use of animals.

Human Capital Management

As of December 31, 2025, we employed 128 full-time employees, 78 of whom are involved in sales and marketing activities, 7 of whom are involved in research and development activities and 43 of whom are involved in general and administrative activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement.

We continually evaluate business needs and opportunities in addition to balancing in-house expertise and capacity with that of outsourced resources. Currently, we outsource drug manufacturing work to contract manufacturers in addition to a few other specialty tasks for which we do not have in-house expertise.

Drug development is a complex endeavor that requires deep expertise and experience across a broad array of disciplines. Pharmaceutical companies both large and small compete for a limited number of qualified applicants to fill specialized positions with heavy competition for talent. To attract qualified applicants, we offer a total rewards package consisting of base salary and cash bonus incentive targets aligned with the applicable market norms and long term equity compensation. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Actual bonus payouts for all employees except our executive officers are based on a weighting of Company and individual performance, which varies based on level of responsibility. Actual bonus payout for our executive officers (including our named executive officers for the year ended December 31, 2025) is based exclusively on Company performance, as will be more fully described in our Definitive Proxy Statement to be filed with the SEC related to our 2026 Annual Meeting of Stockholders.

As additional means of attracting and retaining appropriate talent, we offer all employees a robust benefits package offering a comprehensive array of benefits including generous employer contributions toward medical, dental, and vision insurance as well as company paid life and disability insurance coverage. We also offer a retirement savings plan with a company match and an Employee Stock Purchase Plan.

We support our employees' further development with individualized development plans, mentoring, coaching, internal development workshops, and certain financial support, including Company-paid external conference attendance and tuition reimbursement. We sponsor professional society memberships for all employees, as well as memberships for interested female employees in a women's advocacy organization supporting women in Science, Technology, Engineering and Math.

We also monitor employee compliance with applicable laws and regulations through a third-party ethics and compliance hotline system that facilitates anonymous internal and external reporting of complaints or concerns.

We are committed to the safety, health and security of our employees. We believe a hazard-free environment is critical for the success of our business. Throughout our operations, we strive to ensure that all our employees have access to safe workplaces that allow them to succeed in their jobs. Our experience and continuing focus on workplace safety has enabled us to preserve business continuity without sacrificing our commitment to keeping our colleagues safe.

Company Information

Our principal executive offices are located at 100 Regency Forest Drive, Suite 300, Cary, North Carolina 27518, and our telephone number is (858) 251-4400. Our website address is *www.herontx.com*. We make our periodic and current reports, and any amendments to those reports, available on our website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. No portion of our website is incorporated by reference into this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

Risk Factor Summary

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this Annual Report on Form 10-K. If any of the following events, described as risks, actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our securities. An investment in our securities is speculative and involves a high degree of risk. You should not invest in our securities if you cannot bear the economic risk of your investment for an indefinite period of time and cannot afford to lose your entire investment.

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found below.

- We are substantially dependent on the commercial success of our Products, and if these Products do not attain market acceptance by healthcare professionals and patients, our business and results of operations will suffer.
- If we cannot maintain satisfactory pricing of our Products, that is also acceptable to the U.S. government, insurance companies, managed care organizations and other payors, or arrange for favorable reimbursement policies, our product sales may be adversely affected and our future revenue may suffer.
- If we fail to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs, we could be subject to additional reimbursement requirements, penalties and fines, which could have a negative impact on our business, financial condition, and results of operations.
- If our suppliers or contract manufacturers are unable to manufacture in commercially viable quantities, or perform as expected, we could face delays in our ability to commercialize our Products, our costs will increase and sales of our Products, may be severely hindered.
- Certain of the components used in the manufacture of our Products are, or might be, sourced from a single vendor, and the loss or disruption of this vendor could significantly harm our business.
- We face intense competition from other companies developing products for the management of postoperative pain or the prevention of CINV and PONV, including lower-cost generic products, which may limit our ability to sell our products.
- Our product platforms or product development efforts may not produce safe, efficacious or commercially viable products, and, if we are unable to develop new products, our business may suffer.
- If we are unable to recruit and retain skilled employees, we may not be able to achieve our objectives.
- Our business strategy may include international expansion, acquisitions of other businesses, products or product licenses. We may not be able to successfully manage such activities.
- Our business strategy may include entry into collaborative agreements. We may not be able to enter into collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements.
- Natural or man-made disasters, including severe weather, epidemics, pandemics, cyber attacks, acts of war or terrorism, armed conflict, federal workforce uncertainty, or resource shortages, could disrupt our investigational drug candidate development and approved drug commercialization efforts or have other negative consequences on our business and adversely affect results.
- We have a history of losses, we expect to generate losses in the near future, and we may never achieve or maintain profitability.

- Additional capital may be needed in the future to enable us to implement our business plan, and we may be unable to raise capital, which would force us to limit or cease our operations.
- Provisions contained in our debt instruments limit our ability to incur additional indebtedness.
- We could be exposed to significant product liability claims that could be time-consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.
- If any of our services providers are characterized as employees, we would be subject to employment and tax withholding liabilities and other additional costs.
- The investment of our cash is subject to risks, which may cause losses or adversely affect the liquidity of these investments and our results of operations, liquidity and financial condition.
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.
- If we fail to comply with continuing federal, state and foreign regulations with respect to our Products for which we obtain regulatory approval, we could lose our approvals to market drugs, and our business would be seriously harmed.
- The commercial use of our Products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business.
- The pharmaceutical industry is subject to significant regulation and oversight pursuant to anti-kickback laws, false claims statutes and anti-corruption laws, which may result in significant additional expense and limit our ability to commercialize our Products. In addition, any failure to comply with these regulations could result in substantial fines or penalties.
- We may incur significant liability if it is determined that we are promoting the "off-label" use of drugs or promoting in a non-truthful and misleading way.
- Health care reform could increase our expenses and adversely affect the commercial success of our Products.
- Our use of hazardous materials could subject us to liabilities, fines and sanctions.
- Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a negative impact on our business.
- We are and may become subject to stringent and evolving laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.
- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.
- Changes in government policies, laws, and regulations may have a negative impact on our business and the markets in which we operate.
- If we are unable to adequately protect or enforce our intellectual property rights, we may lose valuable assets or incur costly litigation to protect our rights.
- We may be subject to claims that we have infringed on the intellectual property rights of others, and any litigation could force us to stop developing or selling potential products and could be costly, divert management attention and harm our business.

- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- The price of our common stock has been and may continue to be volatile.
- Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.
- Future utilization of net operating loss carryforwards or research and development credit carryforwards may be impaired due to changes in ownership.
- Actions of activist stockholders could impact the pursuit of our business strategies, cause us to incur substantial costs, divert our management's attention and resources, and adversely affect our business, results of operations, liquidity, financial condition, and the trading price of our common stock.
- If we identify a material weakness in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our common stock could be negatively affected.
- Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the source of gain for our stockholders.

Risks Related to Our Business

We are substantially dependent on the commercial success of our Products, and if these Products do not attain market acceptance by healthcare professionals and patients, our business and results of operations will suffer.

The success of our business is substantially dependent on our ability to achieve market acceptance of our Products. Although members of our management team have prior experience launching new drugs, ZYNRELEF, APONVIE, CINVANTI and SUSTOL are the first four products that we have launched.

Further, even if our sales organization performs as expected, the revenue that we may receive from the sales of our Products, may be less than anticipated due to factors that are outside of our control. The factors that may affect revenue include:

- the scope of our approved Product labels, including any expanded indications;
- the perception of physicians and other members of the healthcare community of the safety and efficacy and cost-competitiveness relative to that of competing products;
- our ability to maintain successful sales, marketing and educational programs for certain physicians and other healthcare providers;
- our ability to raise patient and physician awareness of the risks associated with using opioids for postoperative pain management and encourage physicians to consider utilizing a non-opioid alternative;
- our ability to raise patient and physician awareness of CINV associated with AC combination chemotherapy regimens, MEC or HEC and encourage physicians to look for incidence of CINV among patients;
- our ability to raise patient and physician awareness of PONV associated with surgical procedures and encourage physicians to look for incidence of PONV among patients;
- the timing and scope of acceptance of our Products by institutional formulary committees and the amount of time between such acceptance and the first use of our Products within the applicable setting of care;
- patient and physician satisfaction with our Products;
- the size of the potential market for our Products;
- our ability to obtain coverage and adequate reimbursement from government and third-party payors;
- unfavorable publicity concerning our Products or similar products;
- the introduction, availability and acceptance of competing treatments, including competing generic products;
- adverse event information relating to our Products or similar classes of drugs;
- product liability litigation alleging injuries relating to our Products or similar classes of drugs;
- our ability to maintain and defend our patents and trade secrets for our Products and our Biochronomer Technology;
- our ability to continue to have our Products manufactured at commercial production levels successfully and on a timely basis;

- our ability to scale up manufacturing of our Products to meet commercial requirements;
- the availability of raw materials necessary to manufacture our Products;
- our ability to establish and maintain successful commercial arrangements like our co-promotion agreement with Crosslink Network;
- our ability to access third parties to manufacture and distribute our Products on acceptable terms or at all and those third parties' ability and/or willingness to fully perform their obligations;
- regulatory developments related to the manufacture or continued use of our Products;
- conduct of post-approval study requirements and the results thereof;
- the extent and effectiveness of sales and marketing and distribution support for our Products;
- our competitors' activities, including decisions as to the timing of competing product launches, generic entrants, pricing and discounting; and
- any other material adverse developments with respect to the commercialization of our Products.

Our business will be adversely affected if, due to these or other factors, our commercialization of our Products does not achieve the acceptance and demand necessary to sustain revenue growth. If we are unable to successfully commercialize our Products our business and results of operations will suffer.

If we are unable to develop and maintain sales, marketing and distribution capabilities or enter into agreements with third parties to sell and market our Products, our sales may be adversely affected.

We have established an internal commercial organization for the sale, marketing and distribution of our Products in the U.S. The development of a sales organization to market our Products is expensive and time consuming, and we cannot be certain that we will be able to successfully develop this capacity or that this function will execute as expected. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and our business and results of operations will suffer.

Currently, we only have approval to market and sell our Products in the U.S and do not have current plans to expand to international markets. Furthermore, our internal sales and marketing organization is not currently structured or staffed to launch products on an international level and, therefore, we may not be able to successfully commercialize our Products outside of the U.S. In order to commercialize our Products in jurisdictions other than the U.S., we would be required to obtain separate marketing approvals and comply with numerous and varying regulatory requirements in each foreign country. If we decide to seek the assistance of third parties with international expertise to help commercialize our Products outside of the U.S., we may not be successful in finding willing third parties and, even if we are able to find willing third parties, they might not be able to successfully obtain the approvals and take the steps needed to commercialize our Products. If we decide to commercialize our Products outside of the U.S. without the assistance of third parties with international expertise, it may take longer than expected to obtain the approvals and take the steps needed to commercialize them. As a result, we may decide to delay or abandon development efforts in certain markets. Any such delay or abandonment may have an adverse effect on the benefits otherwise expected from marketing our Products in foreign countries.

From time to time, we may enter into additional arrangements with third parties to help commercialize our Products and we would be dependent on the subsequent efforts of these other parties to sell our Products. Currently, we have a co-promotion agreement with Crosslink Network, pursuant to which we have committed to pay Crosslink Network certain agreed-upon compensation to co-promote the sale of certain products and Crosslink Network has been appointed as our exclusive co-promoter of ZYNRELEF within the U.S. If Crosslink Network or any such other third

party fails to perform their obligations as anticipated for any reason, it could adversely impact our financial condition and be detrimental to our future business prospects.

If we cannot maintain satisfactory pricing of our Products that is also acceptable to the U.S. government, insurance companies, managed care organizations and other payors, or arrange for favorable reimbursement policies, our product sales may be adversely affected and our future revenue may suffer.

The continuing efforts of the U.S. government, insurance companies, managed care organizations and other payors of healthcare costs to contain or reduce costs of healthcare may adversely affect our ability to generate adequate revenues and gross margins to make our Products commercially viable. Our ability to commercialize our Products successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of such products and related treatments and for what uses reimbursement will be provided.

Adoption of our Products by the medical community may be limited if third-party payors will not offer adequate coverage. In addition, third-party payors often challenge the price and cost-effectiveness of medical products and services, and such pressure may increase in the future. In many cases, uncertainty exists as to the adequate reimbursement status of newly approved healthcare products. Accordingly, our Products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our Products or product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Legislation and regulations affecting the pricing of pharmaceuticals may change and any such changes could further limit reimbursement. Cost control initiatives may decrease coverage and payment levels for our Products and, in turn, the reimbursement that we receive. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payors to our Products. If our Products do not receive adequate reimbursement, our revenue could be severely limited.

In the U.S., given federal and state government initiatives directed at lowering the total cost of healthcare, the U.S. Congress and state legislatures has continued to focus on healthcare reform, to reduce the cost of prescription pharmaceuticals and reforming the Medicare and Medicaid systems. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA") has resulted in sweeping changes to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the PPACA. The One Big Beautiful Bill Act ("OBBBA") has enacted, among others, changes to enrollment and eligibility requirements for Medicaid and premium tax credits, which has resulted in less coverage in the PPACA's health insurance marketplace ("Marketplace"). Further, CMS recently proposed two mandatory payment model pilots, the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, focused on Part D drugs, and Global Benchmark for Efficient Drug Pricing (GLOBE), focused on Part B drugs, which will require pharmaceutical companies to pay additional rebates on certain medicines, whose U.S. net-of-discount prices exceed those in certain other countries.

The SUPPORT Act of 2018, established policies to encourage the prevention and treatment of opioid addiction and the development of non-opioid pain management treatments. Due to the SUPPORT Act, Medicare pays separately for certain non-opioid pain management drugs in ambulatory surgical centers ("ASC") but not in the hospital outpatient setting ("OPPS"). However, under the Consolidated Appropriations Act of 2023, the prior payment policy was replaced by a new three-year period of separate payment for non-opioid pain relief products in the OPPS and ASC settings for 2025 through 2027. As of January 1, 2025, Medicare has implemented this new payment methodology, which remains in effect through December 31, 2027. ZYNRELEF is included in this new policy, as of April 1 2025, which means continued separate Medicare payment in the OPPS and ASC settings. While this change may improve access to ZYNRELEF, it may also lead to greater competition.

The American Rescue Plan Act of 2021, removed the statutory cap on rebates that manufacturers pay to state Medicaid programs pursuant to the Medicaid Drug Rebate Program. The Infrastructure Investment and Jobs Act of 2021 also included a provision requiring drug manufacturers to pay CMS a refund for certain amounts of Part B drugs that are discarded from a single-dose container or single-use package. Under the law, and a CMS Proposed Rule issued in July 2022, this refund program became effective on January 1, 2023. Such legislation did not have a material impact on the Company, through December 31, 2025.

Further, the Inflation Reduction Act of 2022 ("IRA"), includes various provisions intended to address drug-pricing issues which requires manufacturers to engage in the drug price negotiation program with Medicare or face steep penalties if they don't agree to provide their drug at the government-set price subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; establishes an out-of-pocket maximum for beneficiaries in Part D; and replaces the Part D coverage gap discount program with a new discounting program. If any of our Products are subject to price negotiations, it could, among other things, lead to lower revenues prior to the expiry of intellectual property protections.

In addition, developments in Medicare hospital outpatient reimbursement for 340B-acquired drugs may further drive 340B hospital business for Heron. The 340B program allows certain hospitals and safety net providers to purchase Part B outpatient drugs from manufacturers at federally mandated discounted rates. Due to the June 2022 Supreme Court decision in American Hospital Association et al. v. Becerra et al, since January 1, 2023, the Medicare Part B hospital outpatient payment rate for 340B-acquired drugs has returned to being at the same rate as the rate for non-340B hospitals, Average Selling Price (ASP) + 6% methodology. However, pursuant to Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, CMS announced that it will conduct a new mandatory Medicare OPPS Drug Acquisition Cost Survey from January 1, 2026, through March 31, 2026. CMS has stated that this survey will inform potential changes to payment policy beginning with the calendar year 2027 OPPS/ASC proposed rule. These actions indicate that future adjustments to Medicare payment rates for 340B‑acquired drugs may be under consideration, which could affect reimbursement dynamics for the Company's products purchased under the 340B program in hospital outpatient settings.

We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on drug prices, which may affect prices of our Products in the future. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to price our Products at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize our product candidates, if approved.

Moreover, economic pressure on state budgets have resulted in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. For example, individual states in the U.S. have become increasingly active in implementing regulations through state Pharmacy Drug Review Boards designed to contain drug pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. State Medicaid programs are increasingly asking manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. In addition, the trend toward managed healthcare in the U.S., which could significantly influence the purchase of healthcare services and products, may result in lower prices for our Products.

Further, executive orders were signed to implement Most Favored Nation drug pricing policies designed to align certain prescription drug prices in the U.S. to lower prices available in other countries. Investigations are being conducted to examine price differentials and consider policy approaches for implementation, including through administrative action. If such Most Favored Nation policies are implemented, changes to drug pricing are expected to affect the profitability of pharmaceutical and biotech companies in the U.S. as well as in other countries, as a price referencing policy to the U.S. market could make it commercially unviable to commercialize a drug product in a price constrained market. The details of the proposed policies are unclear and the final terms and impact remain uncertain, and may pose long-term risks to our business and our future commercialization plans of our Products and

product candidates. In addition, the Fair Prescription Drug Prices for Americans Act was re-introduced in May 2025 and proposes to cap the retail list price of prescription drugs and biological products in the United States at the average retail list price for such product among certain countries.

Finally, in December 2025, the BIOSECURE Act was signed into law as part of the National Defense Authorization Act, which restricts U.S. government agencies from purchasing or obtaining certain biotechnology equipment or services from "biotechnology companies of concern" ("BCC"); entering, extending or renewing a contract with any entity using biotechnology equipment or services provided by a BCC to perform a government contract; or granting government funds or loans for such biotechnology equipment or services provided by a BCC. The BIOSECURE ACT may have significant implications for U.S. companies with government contracts that obtain biotechnology equipment or services from a BCC, including contracts with the Department of Veterans Affairs, and any related impact on reimbursement under Medicaid and Medicare Part B. While we do not currently anticipate any material impact from the BIOSECURE Act, evolving regulatory requirements may introduce additional operational and contracting obligations over time.

While we cannot predict the impact of such legislative or regulatory changes on our business, the announcement or adoption of these proposals could have a material and adverse effect on our potential revenues and gross margins.

If we fail to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs, we could be subject to additional reimbursement requirements, penalties and fines, which could have a negative impact on our business, financial condition, and results of operations.

The Medicare program and certain government pricing programs, including the Medicaid drug rebate program, the Public Health Services' 340B drug pricing program, and the pricing program under the Veterans Health Care Act of 1992 impact the reimbursement we may receive from sales of our Products, or any other products that are approved for marketing in the U.S. Pricing and rebate calculations vary among programs. The calculations are complex and are often subject to interpretation by manufacturers, governmental or regulatory agencies and the courts. We are required to submit a number of different pricing calculations to government agencies on a quarterly basis. Failure to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs may result in additional payments, penalties and fines due to government agencies, which could negatively impact our business, financial condition and results of operations.

If our suppliers or contract manufacturers are unable to manufacture in commercially viable quantities, we could face delays in our ability to commercialize our Products, our costs will increase and sales of our Products , may be severely hindered.

The commercial success of our Products are dependent on the ability of our contract manufacturers to produce a product in commercial quantities at competitive costs of manufacture in a process that is validated by the FDA. We have scaled up manufacturing for CINVANTI and ZYNRELEF in order to realize important economies of scale, and these activities took time to implement, required additional capital investment, process development and validation studies and regulatory approval. We cannot guarantee that we will be successful in achieving competitive manufacturing costs through such scaled-up activities or that our contract manufacturers will perform their obligations. In addition, our manufacturing agreements include payment terms that require significant cash payments at specified times, and if we are unable to make the required payments at the required times, we are at risk of default under the agreements, which would severely hinder our ability to procure adequate amounts of our Products.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise, including product loss due to material failure, equipment failure, vendor error, operator error, labor shortages, inability to obtain material, equipment or transportation, physical or electronic security breaches and natural or man-made disasters. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products or recall products previously shipped, or could impair our ability to expand into new markets or supply products in existing markets. We may not be able to resolve any such problems in a timely manner, if at all.

We depend on third-party suppliers and contract manufacturers to manufacture our Products, and we expect to do the same for any future products that we develop; if our contract manufacturers do not perform as expected, our business could suffer.

We do not own or operate manufacturing facilities for the production of commercial or clinical quantities of any product, including our Products. Our ability to successfully commercialize our Products depends in part on our ability to arrange for, and rely on, other parties to manufacture our products at a competitive cost, in accordance with regulatory requirements, and in sufficient quantities for clinical testing and commercialization. We currently rely on a small number of third-party manufacturers to produce compounds used in our Products. Certain contract manufacturers are, at the present time (and are expected to be for the foreseeable future), our sole resource to manufacture certain key components of our Products. Although we entered into long-term commercial manufacturing agreements for the manufacture of our Products, including long-term agreements for the manufacture of our Biochronomer Technology, we might not be able to successfully negotiate long-term agreements with any additional third parties, or we might not receive all required regulatory approvals to utilize such third parties, and, accordingly, we might not be able to reduce or remove our dependence on a single supplier for the commercial manufacturing of our Products. We may have difficulties with these manufacturer relationships, and we may not be able to find replacement contract manufacturers on satisfactory terms or on a timely basis. At times, our contract manufacturers or other third parties might not perform their obligations under long-term commercial manufacturing agreements or other agreements, which could impede the manufacturing of our Products and could require us to incur additional costs, including legal fees, as we seek to enforce our contractual rights. Our reliance on third-party suppliers and contract manufacturers also subjects our business to risks associated with geographic areas in which those parties reside, which could include natural or man-made disasters, including severe weather, epidemics, pandemics, acts of war or terrorism, armed conflict or resource shortages. Due to regulatory and technical requirements, we may have limited ability to shift production to a different third-party should the need arise. We cannot be certain that we could reach agreement on reasonable terms, if at all, with such a manufacturer. Even if we were to reach agreement, the transition of the manufacturing process to a different third-party could take a significant amount of time and money and may not be successful.

Further, we, along with our contract manufacturers, are required to comply with FDA and foreign regulatory requirements related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may not be able to comply with the applicable FDA or foreign regulatory requirements. They may be required to pass an FDA pre-approval inspection for conformity with cGMP before we can obtain approval to manufacture our Products and our product candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP, or fail to scale up manufacturing processes in a timely manner, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our product candidates, cost overruns or other problems that could seriously harm our business. For instance, our third party suppliers and contract manufacturers have produced drug products that do not meet our specifications and quality standards. We have, and may in the future, be required to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts, experience delays that affect our operations and commercialization plans or seek more costly manufacturing alternatives. Not complying with FDA or foreign regulatory requirements could result in an enforcement action, such as a product recall, or prevent commercialization of our product candidates and delay our business development activities. In addition, such failure could be the basis for the FDA or foreign regulators to issue a warning or untitled letter or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

Our Products may be in competition with other products for access to the facilities of third parties and, consequently, could be subject to manufacturing delays if our contractors give other companies' products greater priority than ours. Additionally, our contractors might be required by government regulation or government authority to prioritize production of other products. For this and other reasons, our third-party contract manufacturers may not be able to manufacture our Products in a cost-effective or timely manner. If not

manufactured in a timely manner, the manufacture of any of our Products or their submission for regulatory approval could be delayed, and our ability to deliver products to market on a timely basis could be impaired. This could increase our costs, cause us to lose revenue or market share and damage our reputation.

Certain of the components used in the manufacture of our Products are, or might be, sourced from a single vendor, and the loss or disruption of this vendor could significantly harm our business.

Some of the critical materials and components used in manufacturing our Products are, or might be, sourced from single suppliers. An interruption in the supply of a key material could significantly delay or increase our expenses for commercialization or development products. Specialized materials must often be manufactured for the first time for use in drug delivery technologies, or materials may be used in these technologies in a manner different from their customary commercial uses. The quality of materials can be critical to the performance of a drug delivery technology, so a reliable source that provides a consistent supply of materials is important. Materials or components needed for our drug delivery technologies may be difficult to obtain on commercially reasonable terms, particularly when relatively small quantities are required or if the materials traditionally have not been used in pharmaceutical products. Our reliance on a single vendor for certain components used in the manufacturing of our Products also subjects our business to risk associated with the geographic areas in which those single vendors reside, which could include natural or man-made disasters, including severe weather, epidemics, pandemics, acts of war or terrorism, armed conflict, resource shortages or geopolitical instability, including as a result of increased tariffs and changing regulations and policies that may disrupt global markets or escalate tensions between countries. Such adverse events could cause global supply chain interruptions that could increase our costs and, to the extent such interruptions impair our ability to have sufficient inventory, cause us to lose revenue or market share. We continually evaluate our supply chains to identify potential risks and needs for additional manufacturers and other suppliers for the manufacturing of our Products. Establishing additional or replacement suppliers for certain raw materials in our proprietary polymers, if required, may not be accomplished quickly, or at all, and may involve significant expense. If we are able to find a replacement supplier, we would need to evaluate and qualify such replacement vendor and its ability to meet quality and compliance standards. Any change in suppliers or the manufacturing process for our Products could require additional regulatory approval and result in operational delays.

Some of our suppliers may experience disruption to their respective supply chains due to the adverse events or conditions, including the effects of a pandemic or disease outbreak, the imposition of tariffs and other trade protective measures, rising geopolitical tensions, armed conflict, regulatory and policy changes or other factors, which could delay, prevent or impair our development or commercialization efforts.

We obtain certain critical materials and components used in manufacturing our Products from third-party suppliers whose operations might be directly or indirectly affected by adverse events or conditions, including the effects of a pandemic or disease outbreak, the imposition of tariffs and other trade protective measures, rising geopolitical tensions and political instability, armed conflict, regulatory or policy changes, adverse weather conditions and public fears regarding any of the foregoing. For example, the increase in tariffs between the U.S. and certain countries has escalated geopolitical tensions and may significantly disrupt the global markets and supply chains. Tensions between mainland China and Taiwan have further escalated, with China accelerating the development of military capabilities and threatening the use of military force to gain control over Taiwan in certain circumstances. Similarly, geopolitical conflicts in Russia and Ukraine, the Middle East, South America and elsewhere remain unpredictable and could escalate into a broader armed conflict and additional economic sanctions or countermeasures by the affected countries or others, which could exacerbate market and economic instability. If we are unable to obtain these critical materials and components in sufficient quantities and in a timely manner, the manufacture, development, testing and clinical study of our Products might be delayed or infeasible, which could significantly harm our business.

We have, or may have, significant inventory levels of drug products, and write-downs related to the impairment of those inventories may adversely impact or delay our profitability.

We have, or may have, significant inventory levels of drug products, and we may increase those inventory levels as we continue to commercialize our Products. We determine inventory levels of drug products based on a variety of estimates, including timing of regulatory approval of our drug products, market demand for our drug products and those of our competitors, entrance of competing drug products, introduction of new, or changes in interpretations of,

pharmaceutical regulations, and changes in healthcare provider and insurer reimbursement policies. These estimates are inherently difficult to make and may be inaccurate. We analyze our inventory levels and will write down inventory that has become obsolete. If our initial estimate of the appropriate inventory levels of drug products is or becomes inaccurate, write-downs of inventory may be required, which would be recorded as cost of product sales and thereby adversely impact or delay our profitability.

It is difficult to predict commercial demand for our Products, and, if our estimates of demand are too low, it may adversely impact our ability to generate revenue and profits in the short term and our ability to establish and maintain a competitive position in the relevant markets where our Products are sold, or may be sold, in the future.

Despite our efforts to maintain appropriate inventory levels of our Products, as we continue to commercialize our Products, our estimates of appropriate inventory levels may not be accurate. If we fail to build up sufficient inventory levels to meet commercial demand, our ability to generate revenue and profits in the short term would be adversely impacted. Failure to meet demand may also cause us to lose market share to our competitors, which could materially and adversely affect our business, financial condition, cash flows and results of operations. Given the time required to scale production and replenish inventory, our ability to correct for inaccurate estimates in a timely manner may be limited.

We face intense competition from other companies developing products for the management of postoperative pain or the prevention of CINV and PONV, which may limit our ability to sell our Products.

ZYNRELEF competes in the postoperative pain management market with MARCAINETM (bupivacaine hydrochloride injection, solution, marketed by Pfizer Inc.) and generic forms of bupivacaine; NAROPIN® (ropivacaine, marketed by Fresenius Kabi USA, LLC) and generic forms of ropivacaine; EXPAREL® (bupivacaine liposome injectable suspension, marketed by Pacira BioSciences, Inc.); XARACOLL®(bupivacaine HCl implant, marketed by Innocoll Pharmaceuticals Limited); POSIMIR® (owned by Durect Corporation and to be marketed in the U.S. by Innocoll Pharmaceuticals Limited); ANJESO® (meloxicam injection, marketed by Baudax Bio, Inc.); OFIRMEV® (acetaminophen injection, marketed by Mallinckrodt Pharmaceuticals); SEGLENTIS® (celecoxib and tramadol hydrochloride, marketed by Kowa Pharmaceuticals America, Inc. in the U.S.); generic forms of IV acetaminophen; and potentially other products in development for postoperative pain management that reach the U.S. market.

APONVIE competes in the PONV prevention market with generic ondansetron, the current standard of care, generic aprepitant, and BARHEMSYS® (amisulpride, marketed by Eagle Pharmaceuticals, Inc.); TAK-951 (a peptide agonist under development (PH2) by Takeda Pharmaceutical Company Limited for PONV and not approved anywhere globally for any use); and potentially other products in development for PONV prevention that reach the market.

CINVANTI faces significant competition. NK1 receptor antagonists are administered for the prevention of CINV, in combination with 5-HT3 receptor antagonists, to augment the therapeutic effect of the 5-HT3 receptor antagonist. Currently available NK1receptor antagonists include: generic versions of EMEND® IV (fosaprepitant); EMEND® IV (fosaprepitant, marketed by Merck & Co., Inc.); EMEND® (aprepitant, marketed by Merck & Co., Inc.); AKYNZEO®(palonosetron, a 5-HT3 receptor antagonist, combined with netupitant, an NK1 receptor antagonist, marketed by Helsinn Therapeutics (U.S.), Inc.); VARUBI® (rolapitant, marketed by TerSera Therapeutics LLC), FOCINVEZ™ (fosaprepitant injection, marketed by Amneal Pharmaceuticals, LLC) and other products that include an NK1 receptor antagonist that reach the market for the prevention of CINV.

SUSTOL faces significant competition. Currently available 5-HT3 receptor antagonists include: AKYNZEO® (palonosetron, a 5-HT3 receptor antagonist, combined with netupitant, an NK1 receptor antagonist, marketed by Helsinn Therapeutics (U.S.), Inc.); SANCUSO® (granisetron transdermal patch, marketed by Cumberland Pharmaceuticals Inc.); and generic products including ondansetron (formerly marketed by GlaxoSmithKline plc as ZOFRAN), granisetron (formerly marketed by Hoffman-La Roche, Inc. as KYTRIL) and palonosetron (formerly marketed by Eisai in conjunction with Helsinn Healthcare S.A. as ALOXI) and Posfrea (Palonosetron Injection, marketed by AVYXA). Currently, palonosetron is the only 5-HT3receptor antagonist other than SUSTOL that is approved for the prevention of delayed CINV associated with MEC regimens. SUSTOL is indicated in combination

with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens, which is considered to be a HEC regimen by the NCCN and ASCO. No other 5-HT3 receptor antagonist is specifically approved for the prevention of delayed CINV associated with a HEC regimen.

Small or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. We will also face competition from these parties in establishing clinical trial sites and patient registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their product candidates sooner than we do for our product candidates that are more effective or less costly than ours, our commercial opportunity could be significantly reduced. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development of technologically improved or different products or drug delivery technologies may make our product candidates or platform technologies obsolete or noncompetitive.

Our Products may face competition from lower-cost generic products offered by our competitors, which may limit our ability to sell our Products or require us to reduce our pricing.

Pricing for therapeutics can be extremely competitive, and strict formulary guidelines enforced by payors may create significant challenges in the acceptance and profitability of branded products. The market for generic products can be very lucrative, and it is dominated by companies that may have much larger distribution capabilities than we may have in the future. It can be very difficult to predict the timing of the launch of generic products given the commonality of litigation with manufacturers over anticipated patent expiration. Our inability to accurately foresee and plan for generic product launches that may compete with our Products may significantly impact our potential revenues from such Products. On the expiration or loss of patent protection for a branded product, or on the "at-risk" launch (despite pending patent infringement litigation against the generic product) by a manufacturer of a generic version of a drug that may compete with one of our products, we could quickly lose a significant portion of our sales of that Product. The inability for a branded Product we may sell to successfully compete against generic products could negatively impact sales of our Product, reduce our ability to grow our business and significantly harm our business prospects.

For example, we may face competition from newly developed generic products as the Hatch-Waxman Act seeks to stimulate competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. Currently, two companies are seeking approval via an Abbreviated New Drug Application ("ANDA") in the United States for CINVANTI and one company is seeking approval via a 505(b)(2) application in the United States based on CINVANTI. If the Company is unsuccessful in demonstrating infringement of its patents by an ANDA or 505(b)(2) product, or the validity of the Company’s patents is successfully challenged, cheaper ANDA or 505(b)(2) versions of our products may be launched commercially and may compete with CINVANTI, as they may be favored by insurers and third-party payors, which would significantly harm our business.

Our business and results of operations may suffer as a result of changes in our pricing or marketing strategies.

In an effort to remain competitive in the marketplace, we can determine, from time to time, to change our pricing or marketing strategies for our approved Products, including by altering the amount or availability of discounts or rebates for any of our approved Products. Any such changes could have short-term or long-term negative impacts on our revenues, which would cause our business and results of operations to suffer. Price increases or changes to our marketing strategies may also negatively affect our reputation and our ability to secure and maintain reimbursement coverage for our approved Products, which could result in decreased demand and cause our business and results of operations to suffer.

Guidelines and recommendations published by various organizations could reduce the demand for or use of our Products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our Products. In addition, professional societies, practice management groups, private health and science foundations and other organizations from time to time may publish papers, guidelines or recommendations to the healthcare and patient communities with respect to specific products or classes of products. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines that do not recognize a Product, suggest limitations or inadequacies of a Product or suggest the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use or adoption of any of our Products which could have an adverse impact on our business, financial condition and results of operations.

Because the results of preclinical studies and clinical trials are not necessarily predictive of future results, we can provide no assurances that our Products or product candidates will have favorable results in future studies or receive regulatory approval or expansion of approved indications.

Positive results from preclinical studies or clinical trials should not be relied on as evidence that later or larger-scale studies will succeed. Even if our Products or product candidates achieve positive results in early-stage preclinical studies or clinical studies, we will be required to demonstrate that they are safe and effective for use in Phase 3 studies before we can seek expanded indications or regulatory approvals for their commercial sale. Even if our early-stage preclinical studies or clinical studies achieve the specified endpoints, the FDA may determine that these data are not sufficient to allow the commencement of Phase 3 studies. There is an extremely high historical rate of failure of product candidates proceeding through clinical trials in our industry. There is no guarantee that the efficacy of any of our product candidates shown in early patient studies will be replicated or maintained in future studies and/or larger patient populations. Similarly, favorable safety and tolerability data seen in short-term studies might not be replicated in studies of longer duration and/or larger patient populations. If any Product or product candidate demonstrates insufficient safety or efficacy in any preclinical study or clinical trial, we would experience potentially significant delays in, or be required to abandon, development of that Product for an expanded indication, or product candidate for approval. In addition, product candidates in Phase 3 studies may fail to show the desired safety and efficacy despite having progressed through preclinical and earlier stage clinical trials, which could delay, limit or prevent regulatory approval. Further, data obtained from pivotal clinical studies are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Regulatory approval may also be delayed, limited or prevented by other factors. If we delay or abandon our efforts to develop any of our Products for expanded indications, or product candidates for approval, we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

Interim, topline or preliminary data from our clinical trials that we announce or publish may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

We may publicly disclose interim, topline, or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain expanded indications for our Products, or to obtain approvals for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Although the FDA might grant Fast Track, Breakthrough Therapy and Priority Review or similar designations to our Products and product candidates, there can be no assurance that any of our Products or product candidates that receive similar designations in the U.S. or in any other regulatory jurisdictions will receive regulatory approval any sooner than other Products or product candidates that do not have such designations, or at all.

Fast Track designation is intended to facilitate the development and expedite the review of new therapies to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with the FDA. Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat serious conditions and for which preliminary clinical evidence indicates substantial improvement over available therapies on clinically significant endpoint(s). Priority Review designation is for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment or prevention of serious conditions. Product candidates that receive Fast Track or Breakthrough Therapy designation may receive more frequent interactions with the FDA regarding the product candidate's development plan and clinical trials and may be eligible for the FDA's Rolling Review and Priority Review. Priority Review designation is intended to direct overall attention and resources of the FDA to the evaluation of such applications and means that the FDA's goal is to take action on such applications within six months, compared to 10 months under standard review. We can provide no assurances that any of our Products or product candidates that receive Fast Track, Breakthrough Therapy, Priority Review or similar designations in the U.S. or in any other regulatory jurisdictions will receive regulatory approval any sooner than other Products or product candidates that do not have such designations, or at all. The FDA or any foreign regulatory authorities may also withdraw or revoke Fast Track, Breakthrough Therapy, Priority Review or similar designations, or elect to treat designated candidates in a manner different from what was originally indicated, if they determine that any of our Products or product candidates that receive such designations no longer meet the relevant criteria. Failure to realize the potential benefits of these designations could materially and adversely affect our business, financial condition, cash flows and results of operations.

Our product platforms or product development efforts may not produce safe, efficacious or commercially viable products, and, if we are unable to develop new products, our business may suffer.

Our long-term viability and growth will depend on the successful development of products through our research and development activities. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in preclinical work or early-stage clinical trials does not ensure that later-stage or larger-scale clinical trials will be successful. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors, including protocol design, regulatory and IRB approval, the rate of patient enrollment in clinical trials and compliance with extensive cGCP.

In addition, because we fund the development of our Products and product candidates, we may not be able to continue to fund all such development efforts to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals, or market any approved products. If our drug delivery technologies or product development efforts fail to result in the successful development and commercialization of our Products and product candidates, or if our new Products do not perform as anticipated, such events could materially and adversely affect our business, financial condition, cash flows and results of operations.

We rely on third parties to conduct our preclinical testing and conduct our clinical trials, and their failure to perform their obligations in a timely and competent manner may delay development and commercialization of our Products and product candidates and our business could be substantially harmed.

We have used contract research organizations ("CROs") to oversee or provide selected services for our clinical trials for our Products and our product candidates, and we expect to use the same or similar organizations for our future clinical trials and pipeline programs. There can be no assurance that these CROs will perform their obligations at all times in a competent or timely fashion, and we must rigorously oversee their activities in order to be confident in their conduct of these trials on our behalf. If the CROs fail to commit resources to our Products or product candidates, our clinical programs could be delayed, terminated or unsuccessful, and we may not be able to obtain initial or expanded regulatory approvals for, or successfully commercialize, them. Different cultural and operational issues in foreign countries could cause delays or unexpected problems with patient enrollment or with the data obtained from those locations. If we experience significant delays in the progress of our clinical trials or experience doubts with respect to the quality of data derived from our clinical trials, we could face significant delays in gaining necessary product approvals.

We also rely on third parties to assist in conducting our preclinical studies in accordance with GLP and the Animal Welfare Act requirements. We, our CROs and other third parties are required to comply with cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities. Regulatory authorities enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCP, the clinical data generated in the clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that on inspection by a given regulatory authority, such regulatory authority will determine that any of our ongoing or future clinical trials comply with cGCP. In addition, all of our clinical trials must be conducted with product produced under cGMP. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would increase our related expenses and delay the regulatory approval process.

Our CROs and other third parties we may engage to support our development programs are not our employees, and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical and preclinical programs. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner, or may fail to perform at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the preclinical results or clinical data they obtain is compromised due to the failure to adhere to test requirements, our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our Products and product candidates. As a result, our results of operations and the commercial prospects for our Products and product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If we are unable to recruit and retain skilled employees, we may not be able to achieve our objectives.

We depend on a small number of key management and personnel, including our Chief Executive Officer. Retaining our current employees and recruiting qualified personnel to perform future research and development and commercialization work will be critical to our success. Competition is always present for highly skilled and experienced personnel, and an inability to recruit or retain sufficient skilled personnel could result in delays in our business growth and development and adversely impact our research and development or commercial activities. If we lose key members of our senior management team, we may not be able to find suitable replacements and our business may be harmed as a result. If we fail to adequately address any of the issues referred to above, it could adversely impact our ability to recruit and retain our skilled employees which may result in a material adverse effect on our business, operating results and financial condition.

Our business strategy may include acquisitions of other businesses, products or product licenses. We may not be able to successfully manage such activities.

We may engage in strategic transactions that could cause us to incur contingent liabilities, commitments or significant expense. In the course of pursuing strategic opportunities, we may evaluate potential acquisitions, licenses or investments in strategic technologies, products or businesses. Future acquisitions, licenses or investments could subject us to a number of risks, including, but not limited to:

- our inability to appropriately evaluate and take into consideration the potential uncertainties associated with the other party to such a transaction, including, but not limited to, the prospects of that party and their existing products or product candidates and regulatory approvals;

- difficulties associated with realizing the perceived potential for commercial success with respect to any acquired or licensed technology, product or business;

- our ability to effectively integrate any new technology, product and/or business including personnel, intellectual property or business relationships into our Company;

- our inability to generate revenues from acquired or licensed technology and/or products sufficient to meet our objectives in undertaking the acquisition or license or even to offset the associated acquisition and maintenance costs and/or assumption of liabilities; and

- the distraction of our management from our existing product development programs and initiatives in pursuing an acquisition or license.

In connection with an acquisition or license, we must estimate the value of the transaction by making certain assumptions that may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of a transaction. Any strategic transaction we may pursue may not result in the benefits we initially anticipate, may result in costs that end up outweighing the benefits and may adversely impact our financial condition and be detrimental to our future business prospects.

Our business strategy may include entry into collaborative agreements. We may not be able to enter into collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements.

Our business strategy may include the entry into collaborative agreements for the development and commercialization of our Products. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well as the collaborators' own internal product opportunities. We may not be able to consummate collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements.

If we do enter into such arrangements, we could be dependent on the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to researching our product candidates pursuant to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

Under agreements with any collaborators we may work with in the future, we may rely significantly on them to, among other activities:

- fund or perform research and development activities with us or independently;

- diligently pursue regulatory approvals in certain territories;
- pay us fees on the achievement of milestones; and
- market for or with us any commercial products that result from our collaborations.

If we do not consummate collaborative agreements, we may use our financial resources more rapidly on our product development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a negative impact on our business prospects. Further, we may not be successful in overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative relationships, our business prospects could suffer.

Natural or man-made disasters, including severe weather, epidemics, pandemics, cyber attacks, acts of war or terrorism, armed conflict, federal workforce uncertainty, or resource shortages, could disrupt our investigational drug candidate development and approved drug commercialization efforts or have other negative consequences on our business and adversely affect results.

Our ongoing or planned clinical studies and approved drug commercialization efforts could be delayed or disrupted indefinitely on the occurrence of a natural or man-made disaster, including severe weather, an epidemic, a pandemic, or other disease outbreak, cyberattacks, acts of war or terrorism, armed conflict, or resource shortages. We are also vulnerable to damage from other disasters, such as power losses, fires, earthquakes, floods, hurricanes and similar events. Any such natural or man-made disaster, including severe weather, an epidemic, a pandemic, or other disease outbreak, cyberattacks, acts of war or terrorism, armed conflict, and the resulting damage could negatively impact enrollment and participation in our clinical studies, divert attention and resources at our research sites, cause unanticipated delays in the collection and receipt of data from our clinical studies, cause unanticipated delays in communications with, and any required approvals from, the FDA, European Medicines Agency, United Kingdom's Medicines and Healthcare Products Regulatory Agency, Health Canada, and other regulatory authorities, and cause unanticipated delays in the manufacturing and distribution of our Products. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial condition.

Further, recent geo-political conflicts have created extreme volatility in the global financial markets and are expected to have further global economic consequences, including continued disruptions of the global supply chain and energy markets and heightened volatility of commodity prices. Any such instability or disruption may have adverse consequences on us or the third parties on whom we rely, including as a result of a general downturn in global economic conditions, changes in government regulations, deterioration in the credit or equity markets, or more direct impacts on operational matters. This conflict may also give rise to or amplify the other risks described herein including risks relating to cybersecurity, global economic conditions, government regulations and supply chains, which could adversely affect our business, operations and financial condition and results.

Our potential international expansion of our business may expose us to new business, regulatory, political, operational, financial and economic risks associated with such expansion and could adversely affect our business, financial condition, results of operations and growth.

If our Products are marketed internationally by us or a potential third-party partners, we and such third-party partners could be subject to additional risks related to operating in foreign countries, including:

- general economic conditions and monetary and fiscal policy, including economic weakness or inflation;
- financial risks, such as longer payment cycles, difficulty in collecting from international customers, pricing and insurance regimes, unexpected changes in tariffs, trade barriers, and exposure to foreign currency exchange rate fluctuations and controls, which could result in increased operating expenses and reduced revenue, and the effect of local and regional financial crises;

- conflicting and changing laws and regulations, including tariffs and export and import restrictions;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad, if applicable;
- logistical challenges resulting from distributing our Products to foreign countries; and
- economic or business interruptions resulting from civil unrest or social, political, economic, or diplomatic developments, including geo-political actions, such as armed conflict or terrorism.

These and other risks associated with international operations may compromise our ability to earn revenue from arrangements with potential third-party partners for our Products and, therefore, could adversely affect our business, operations and planned international expansion.

Risks Related to Our Financial Condition

We have a history of losses, we expect to generate losses in the near future, and we may never achieve or maintain profitability.

We have incurred significant operating losses and negative cash flows from operations and had an accumulated deficit of $1.9 billion through December 31, 2025. The amount we spend will impact our profitability. Our spending will depend, in part, on:

- the commercial success of our Products;
- the cost of possible acquisitions of technologies, compounds, product rights or companies;
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;
- the costs and impacts of current and potential future litigation; and
- the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees may be intense.

To achieve and sustain profitability, we must, alone or in cooperation with others, successfully develop, obtain regulatory approval for, manufacture, market and sell our Products, including our current work commercializing our Products. We have incurred substantial expenses in our efforts to develop and commercialize our Products and we may never generate sufficient revenue to become profitable or to sustain profitability.

Additional capital may be needed in the future to enable us to implement our business plan, and we may be unable to raise capital, which would force us to limit or cease our operations.

As of December 31, 2025, we had cash, cash equivalents and short-term investments of $46.6 million and indebtedness under our Working Capital Facility Agreement, dated August 9, 2023 with Hercules Capital, Inc., as administrative agent, collateral agent, and lender, as amended (the "Working Capital Facility Agreement") and our senior unsecured convertible notes due 2031 (the "2031 Convertible Notes") totaling $147.1 million. Historically, we have financed our operations, including technology and product research and development, primarily through Product sales and equity and debt financings.

Our capital requirements and liquidity going forward will depend on numerous factors, including but not limited to:

- the degree of commercial success of our Products and our product candidates, if approved;
- the timing and cost to manufacture our Products and our product candidates;
- the magnitude and scope of our research and development programs;
- our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing of our product candidates;
- the impact of competitive products;
- the cost of establishing supply arrangements for our Products;
- the cost and timing of establishing or enlarging sales and marketing capabilities;
- the unanticipated delays due to manufacturing difficulties, supply constraints or changes in the regulatory environment, including as a result of geopolitical uncertainty, or other factors; and
- general market conditions.

If we issue additional equity securities or securities convertible into equity securities to raise funds, our stockholders will suffer dilution of their investment, and such issuance may adversely affect the market price of our common stock.

New debt financing we enter into typically involves covenants that restrict our operations. These restrictive covenants may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. In the event that additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or Products on terms that are not favorable to us or require us to enter into a collaboration arrangement that we would otherwise seek to develop and commercialize ourselves. If adequate funds are not available, we may default on our indebtedness, be required to further delay, reduce the scope of, or eliminate one or more of our product development programs and reduce personnel-related and other costs, which would have a negative impact on our business.

Management's view of our liquidity relies on estimates and assumptions about the market opportunity for our Products, which estimates and assumptions are subject to significant uncertainty.

Provisions contained in our debt instruments limit our ability to incur additional indebtedness.

Our Working Capital Facility Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain

exceptions. Our 2031 Convertible Notes also contain provisions that trigger events of default for incurring certain additional indebtedness or any default of our obligations under certain material agreements we may enter into. As a result, we may not be able to raise funds through the issuance of additional debt in the future, which could impair our ability to finance our business obligations or pursue business expansion initiatives.

We could be exposed to significant product liability claims that could be time-consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The administration of drugs in humans, whether in clinical studies or commercially, carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our Products and other products that we may commercially market in the future may cause, or may appear to have caused, injury or dangerous drug reactions, and we may not learn about or understand those effects until the Product has been administered to patients for a prolonged period of time.

Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our Products, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our Products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our Products. A product liability claim could also significantly harm our reputation and delay market acceptance of our Products.

If any of our services providers are characterized as employees, we would be subject to employment and tax withholding liabilities and other additional costs.

We rely on independent third parties to provide certain services to us. We structure our relationships with these outside service providers in a manner that we believe results in an independent contractor relationship, not an employee relationship based on their degree of autonomy and independence in providing certain services. Tax or other regulatory authorities may challenge our characterization of services providers as independent contractors both under existing laws and regulations and under laws and regulations adopted in the future. If such regulatory authorities or state, federal or foreign courts were to determine that our service providers are employees and not independent contractors, we would, among other things, be required to withhold income taxes, to withhold and pay Social Security, Medicare and similar taxes, to pay unemployment and other related payroll taxes, and to provide certain employee benefits. We could also be liable for unpaid past taxes and other costs and subject to penalties. As a result, any determination that the service providers we characterize as independent contractors are determined to be employees could have a negative impact on our business, financial condition and results of operations.

Changes to existing tax laws, or challenges to our tax positions could adversely affect our business and financial condition.

The tax regimes to which we are subject or under which we operate may be subject to significant change. There is uncertainty regarding future legislative and regulatory changes and policies related to matters such as taxation and importation, and any such proposed or enacted regulations by the current or a future U.S. administration, Congress, or taxing authorities in other jurisdictions could materially affect our tax obligations and operating results.
For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the U.S. and over 15 years for research activities conducted outside the U.S. The OBBBA reinstates the option to deduct domestic research and development expenditures in the year incurred, commencing with tax years beginning after December 31, 2024. Foreign research and development expenditures remain subject to the 15-year capitalization and amortization requirement. The OBBBA also includes other significant provisions, including tax cut extensions and modifications to the international tax framework. To the extent that such changes have a negative impact on us, including as a

result of related uncertainty, these changes could adversely impact our business, results of operations and financial position.

In addition, U.S. federal, state and local tax laws are extremely complex and subject to various interpretations. Although we believe that our tax estimates and positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities. If the relevant tax authorities assess additional taxes on us, this could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position.

The investment of our cash is subject to risks, which may cause losses or adversely affect the liquidity of these investments and our results of operations, liquidity and financial condition.

A significant amount of our assets is comprised of cash, cash equivalents and short-term investments. These investments of cash, cash equivalents and short-term investments are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crisis. We may realize losses in the fair value of certain of our investments or a complete loss of these investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and financial condition.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. If any of our counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

Further, any additional deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could result in material losses to us and may material adverse impacts on our business.

Risks Related to Our Industry

Failure to obtain regulatory approval in international jurisdictions would prevent our Products from being marketed abroad.

In the event we pursue the right to market and sell our Products in jurisdictions other than the U.S., we or our potential third-party partners would be required to obtain separate marketing approvals and comply with numerous and varying regulatory requirements in each foreign country. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. In the event we choose to pursue them, we or our potential third-party partners may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our or our potential third-party partners' ability to obtain approval elsewhere. If we or our potential third-party partners are unable in the future to obtain approval of a product candidate by regulatory authorities in non-U.S. jurisdictions, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

If we fail to comply with continuing federal, state and foreign regulations with respect to our Products for which we obtain regulatory approval, we could lose our approvals to market drugs, and our business would be seriously harmed.

Our Products for which we obtain regulatory approval remain subject to ongoing requirements of the FDA and comparable foreign regulatory authorities, including requirements related to manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping, and reporting of safety and other postmarket information. Following initial regulatory approval for drugs we develop, including our Products, we remain subject to continuing regulatory review, including review of adverse drug experiences and clinical results that may be reported after drug products become commercially available. This would include results from any postmarketing tests or continued actions required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a Product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that Product or on the manufacturing facility, including requiring us to withdraw the Product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our contract manufacturers will also be subject to ongoing FDA requirements for submission of safety and other postmarket information. If we and our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;

- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our Products and generate revenue.

Additionally, such regulatory review covers a company's activities in the promotion of its drugs, with significant potential penalties and restrictions for promotion of drugs for an unapproved use or other inappropriate sales and marketing activities. Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, the Department of Justice, and the Department of Health and Human Services' Office of Inspector General. Violations of applicable advertising and promotion laws and regulations, including promotion of products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations and civil and criminal sanctions by the FDA. We are also required to submit information on our open and completed clinical trials to public registries and databases; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business. We are also required to comply with the requirements to submit to governmental authorities information on payments to physicians and certain other third parties. Failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

The commercial use of our Products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business.

We cannot predict whether any commercial use of our product candidates, once approved, will produce undesirable or unintended side effects that have not been evident in clinical trials conducted for such product candidates to date. Additionally, incidents of Product misuse may occur. These events, including the reporting of adverse safety events, among others, could result in Product recalls, product liability actions related to our Products or withdrawals or additional regulatory controls (including additional regulatory scrutiny and requirements for additional labeling), all of which could have a negative impact on our business, financial condition, cash flows and results of operations.

The pharmaceutical industry is subject to significant regulation and oversight pursuant to anti-kickback laws, false claims statutes and anti-corruption laws, which may result in significant additional expense and limit our ability to commercialize our Products. In addition, any failure to comply with these regulations could result in substantial fines or penalties.

We are subject to healthcare fraud and abuse regulations that are enforced by the federal government and the states in which we conduct our business, as well as foreign jurisdictions in which we may conduct business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any drug product with marketing approval. Our future arrangements with 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 with marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include, but are not limited to, the following:

- the Federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. This false claims liability may attach in the event that a company is found to have knowingly submitted false average sales price, best price or other pricing data to the government or to have unlawfully promoted its drug products;

- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") also prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;

- federal "sunshine" laws, now known as Open Payments, that require transparency regarding financial arrangements with healthcare providers, such as the reporting and disclosure requirements imposed by the federal Physician Payments Sunshine Act within PPACA on drug manufacturers regarding any "payment or transfer of value" made or distributed to physicians, other healthcare professionals, and teaching hospitals as well as ownership and investment interests held by such physicians and their family;

- the Drug Supply Chain Security Act ("DSCSA"), which imposes obligations on entities in the commercial product supply chain, including manufacturers, to identify and track prescription drugs as they are distributed in the United States;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state transparency laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, marketing restrictions and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts; and;

- increasingly complex standards for complying with foreign laws and regulations, including those of the EU, that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, certain healthcare reform legislation has strengthened many of these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes to clarify that a person or entity does not need to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides 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 false claims statutes. Finally,

some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs to ensure compliance with these laws.

In addition, a number of states have laws that require pharmaceutical companies to track and report payments, gifts and other benefits provided to physicians and other healthcare professionals and entities.

The FCPA and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. A determination that our operations or activities are not, or were not, in compliance with U.S. or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Changes in laws affecting the healthcare industry could also adversely affect our revenues and profitability, including new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions related to patent protection and enforcement, healthcare availability, and drug product pricing and marketing. Changes in FDA regulations and regulations issued by other regulatory agencies inside and outside of the U.S., including new or different approval requirements, timelines and processes, may also require additional safety monitoring, labeling changes, restrictions on product distribution or other measures that could increase our costs of doing business and adversely affect the market for our Products. The enactment in the U.S. of healthcare reform, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

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 significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, like Medicare and Medicaid, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state and foreign privacy, security and fraud laws may prove costly.

We may incur significant liability if it is determined that we are promoting the "off-label" use of drugs or promoting in a non-truthful and misleading way.

We are prohibited from promoting our Products that receive regulatory approval for "off-label" uses or promoting in a non-truthful and misleading way that are not described in its labeling and that differ from the uses approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across medical specialties. The FDA and other regulatory agencies do not regulate a physician’s choice of treatments. However, they do restrict pharmaceutical companies and their sales representatives’ dissemination of information concerning off-label use. The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of products for off-label uses and the promotion of products for which marketing authorization has not been obtained. A company that is found to have promoted products for off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchanges concerning their products.

The FDA or other regulatory authorities may conclude that we have violated applicable laws, rules or regulations, and we may therefore be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. Such enforcement actions could cause us reputational harm and divert the attention of our management from our business operations. Likewise, our distribution and contracting partners and those providing

vendor support services may also be the subject of regulatory investigations involving, or remedies or sanctions for, off-label promotion of our Products, which may adversely impact sales of our Products or trigger indemnification obligations. These consequences, could, in turn, have a negative impact on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Healthcare reform could increase our expenses and adversely affect the commercial success of our Products.

The U.S. and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

For example, the PPACA includes numerous provisions that affect pharmaceutical companies. The PPACA seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit and an annual fee imposed on all manufacturers of brand prescription drugs in the U.S. The PPACA also requires increased disclosure obligations—including those required under the "sunshine" laws—and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics and contains cost-containment measures that could reduce reimbursement levels for pharmaceutical products. In addition, the IRA extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. These and other aspects of the PPACA, including the regulations that may be imposed in connection with the implementation of the PPACA, could increase our expenses and adversely affect our ability to successfully commercialize our Products.

There have been, and we anticipate that there will be, healthcare reform measures that may be adopted in the future that may result in more rigorous coverage criteria and additional downward pressure on the reimbursement for healthcare products and services. These reform measures may limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payors are willing to pay. Moreover, in the U.S., there have been several presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Conducting clinical trials is a lengthy, time-consuming and expensive process. For example, we incurred significant expenses in developing our Products, with no guarantees that doing so would result in a commercially viable product. Before obtaining regulatory approvals for the commercial sale of any products, we, or our potential partners, must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for their intended uses in humans. We have incurred and will continue to incur substantial expense and devote a significant amount of time to preclinical testing and clinical trials.

The outcome of clinical testing is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. In addition, regulations are not static, and regulatory agencies, including the FDA, alter their staff, interpretations and practices and may in the future impose more stringent requirements than are currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfying regulatory requirements typically takes a significant number of years and can vary substantially based on the type, complexity and novelty of the product candidate. Our business, results of operations and financial

condition could be materially and adversely affected by any delays in, or termination of, our clinical trials. Factors that could impede our ability to generate commercially viable products through the conduct of clinical trials include:

- insufficient funds to conduct clinical trials;
- the inability to find partners, if necessary, for support, including research, development, manufacturing or clinical needs;
- the failure of tests or studies necessary to submit an NDA, such as clinical studies, bioequivalence studies in support of a 505(b)(2) regulatory filing, or stability studies;
- the failure of clinical trials to demonstrate the safety and efficacy of our product candidates to the extent necessary to obtain regulatory approvals;
- the failure by us or third-party investigators, CROs, or other third parties involved in the research to adhere to regulatory requirements applicable to the conduct of clinical trials;
- the failure of preclinical testing and early clinical trials to predict results of later clinical trials;
- any delay in completion of clinical trials caused by a regional, national or global disturbance where we or our collaborative partners are enrolling patients in clinical studies, such as global pandemics and other public health emergencies, war, terrorist activities or political unrest, cyberattacks, a natural or man-made disaster or any other reason or event, resulting in increased costs;
- any delay in obtaining advice from the FDA or similar regulatory authorities; and
- the inability to obtain regulatory approval of our product candidates following completion of clinical trials, or delays in obtaining such approvals.

From time to time, even if a product candidate has not failed, we may voluntarily determine to pause development, which effectively halts our ability to commercialize the product. For example, we decided to pause the development of HTX-034 to evaluate the program and market potential going forward. There can be no assurance that our decisions with respect to such pauses, and subsequent resumptions, if any, will yield the most favorable result for the Company.

There can be no assurance, that if our clinical trials are successfully initiated and completed, we will be able to obtain approval by the FDA in the U.S. or similar regulatory authorities elsewhere in the world in a timely manner, if at all. If we fail to successfully develop and commercialize one or more of our product candidates, we may be unable to generate sufficient revenues to attain profitability, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to significantly decrease.

Delays in, or suspensions and terminations of, clinical testing could increase our costs and delay our ability to obtain regulatory approval for, and commercialize, our product candidates.

Before we can receive regulatory approval for the commercial sale of our product candidates, the FDA and comparable authorities in non-U.S. jurisdictions require extensive preclinical safety testing and clinical trials to demonstrate their safety and efficacy. Significant delays in preclinical and clinical testing could materially impact our product development costs and delay regulatory approval of our product candidates. Our ability to complete clinical trials in a timely manner, or at all, has in the past been, and could in the future be impacted by, among other factors:

- delay or failure in reaching agreement with the FDA or comparable foreign regulatory authority on a trial design that we are able to execute;

- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- delay or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign entities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- delay or failure in obtaining clinical materials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure of subjects completing a trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results or results that are inconsistent with earlier results;
- feedback from the FDA, the IRB, data safety monitoring boards or comparable foreign entities, or results from earlier stage or concurrent preclinical and clinical studies that might require modification to the protocol;
- decisions by the FDA, the IRB, comparable foreign regulatory entities, or recommendations by a data safety monitoring board or comparable foreign regulatory entity to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profiles or unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a drug;
- manufacturing issues, including problems with manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical trials; and
- changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their activities, we have limited influence over CROs' actual performance.

Our failure to successfully establish, recruit for, and oversee our clinical trials could delay our product development efforts and negatively impact our business. If we experience delays in the completion of any ongoing study, the commercial prospects of our product candidates or any of our other future product candidates could be harmed, and our ability to generate product revenue will be delayed. Any delays in completing our clinical trials will increase our costs, slow our product candidates' development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our use of hazardous materials could subject us to liabilities, fines and sanctions.

Our laboratory and clinical testing sometimes involve use of hazardous, radioactive or otherwise toxic materials. We are subject to federal, state and local laws and regulations governing how we use, manufacture, handle, store and dispose of these materials.

Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with all federal, state and local regulations and standards, there is always the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result, and we could also be subject to fines and penalties and such liability and costs could exceed our financial resources. If we fail to comply with these regulations and standards or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial financial liability or be required to suspend or modify our operations. Compliance with environmental and other laws may be expensive and current or future regulations may impair our product development efforts.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a negative impact on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare 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. 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 and results of operations, including the imposition of significant fines or other sanctions.

We are and may become subject to stringent and evolving laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "processing") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions and financial information (collectively, "sensitive data"). Our

data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the U.S., federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the CCPA requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the CPRA, which became operative January 1, 2023, expanded the CCPA's requirements, including applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive data privacy and security laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These developments may further complicate compliance efforts and may increase legal risk and compliance costs for us and the third parties upon whom we rely.

For example, HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Healthcare providers who prescribe our products and from whom we may obtain patient health information are subject to privacy and security requirements under HIPAA. We currently are not a HIPAA covered entity, do not intend to become one, and we do not operate as a business associate to any covered entities. We could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us.

Outside the U.S., an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, GDPR imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern, when required, the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EU or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. In addition, the EU and other jurisdictions have enacted laws restricting the transfer of personal data from the EU and other jurisdictions to the United States due to data localization requirements or limitations on cross-border data flows. Although there are currently various mechanisms that may be used to transfer personal data from the EU and United Kingdom to the United States in compliance with law, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may also be bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant

consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we and the third parties upon which we rely may process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

The increase in remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Further, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We may rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, employee email, and other functions. We may also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their data privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services. We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Changes in government policies, laws, and regulations and with respect to the government workforce may have a negative impact on our business and the markets in which we operate.

The laws and regulations governing our operations, as well as their interpretation, may change from time to time, and new laws and regulations may be enacted. Similarly, operational changes at government agencies, including actions intended to reduce government spending at agencies that regulate significant parts of our business, such as the FDA and CMS, could have a significant impact on the implementation of laws and regulations that impact our business.

For example, the layoffs and reorganizations at several U.S. health agencies, including the FDA, the Department of Health and Human Services (the "HHS"), the Centers for Disease Control and Prevention and the National Institutes of Health, are expected to impact the FDA's ability to review and approve new medicines and conduct necessary inspections. Over the last several years, the U.S. government has also shut down several times and certain regulatory agencies, such as the FDA and SEC, have had to furlough employees, experience substantial funding cuts and pause or delay critical activities. In addition, government funding of 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, and spending allocations may undergo significant changes through congressional budgeting and

appropriations processes. Such disruptions at the FDA and other agencies may also increase the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. There is also a great degree of uncertainty related to the impact of U.S. Supreme Court decisions and executive orders on the enforcement and decision-making authority of regulatory agencies, including those in the FDA, which may lead to delays, if not cancellations, of pending and proposed regulations at federal agencies and subject significant regulatory actions by the agencies to presidential supervision and control.

Accordingly, any change in these laws or regulations, changes in their interpretation, or newly enacted laws or regulations and any failure by us to comply with these laws or regulations could require changes to certain of our business practices, negatively impact our operations, cash flow or financial condition, impose additional costs on us or otherwise adversely affect our business. For example, significant changes to U.S. trade policy, including potential new or increased tariffs, along with countermeasures by the affected countries, may impact global trade, create sourcing challenges with respect to raw materials and instruments and increase our costs, potentially harming our business. The U.S. has imposed increased tariffs on certain countries and other countries have responded by announcing retaliatory tariffs on U.S. imports. The tariffs have disrupted and may continue to disrupt the global markets and escalate geopolitical tensions between the U.S. and other countries. The extent of the impact of such tariffs and proposed regulations on our business specifically, or on the U.S. market and global economy generally, are uncertain and unpredictable, and could adversely affect our business, financial condition and results of operations. Further, the U.S. may also enact other regulations or policies that affect trade or otherwise impact the pharmaceutical industry by restricting U.S. pharmaceutical companies from contracting with certain countries for the development, research or manufacturing of pharmaceutical products. For a discussion on the BIOSECURE Act and related risks, see "Risk Factors - Risks Related to Our Business - If we cannot maintain satisfactory pricing of our Products that is also acceptable to the U.S. government, insurance companies, managed care organizations and other payors, or arrange for favorable reimbursement policies, our product sales may be adversely affected and our future revenue may suffer."

In addition, the U.S. Department of Commerce initiated national security investigations into the importation of pharmaceuticals and pharmaceutical ingredients pursuant to Section 232 of the Trade Expansion Act of 1962, which could result in the imposition of new tariffs on imports within the pharmaceutical industry.

Further, the U.S. announced a 100% tariff on any branded or patented pharmaceuticals imported into the U.S., from drug manufacturers that do not have, or are not in the process of building, a manufacturing facility in the U.S., which has been delayed as negotiations with large drug manufacturers continue. The terms and effects of such tariffs, if and as they are implemented, and other policy changes are uncertain and could have adverse implications on drug pricing, drug production levels and patient access, and may result in supply chain or other operational disruptions. Further, if we are required to change our current manufacturing partners or suppliers now or in the future in order to avoid such tariffs, the terms of new agreements that we may enter into may not be favorable to us and related operational disruptions may heighten manufacturing and compliance risks and derail commercialization plans.

Currently, the various tariffs that have been announced and enacted are not expected to have a material impact on the Company. However, new tariffs or changes in the facts and circumstances impacting the Company could have a material impact to the Company.

Moreover, uncertainty with respect to legislation, regulation and government policy at the federal, state and local levels, has introduced new and difficult-to-quantify macroeconomic and geopolitical risks with potentially far-reaching implications. There are currently a number of laws and regulations in the U.S. that have recently been adopted but not yet implemented, have been proposed or are being considered to which we or our customers may become subject, including healthcare reform initiatives and potential spending and tax proposals, but at this time their impact on our business and results of operations remains uncertain. Changes in legislation, regulation or policy increase the likelihood that we will fail to appropriately adapt to changes in our compliance obligations, particularly when such changes happen abruptly, such as following a change in government. Any of the foregoing changes could

increase our litigation and regulatory exposure, directly impact our results of operations and cash flows, adversely affect our ability to provide our products, or adversely impact the demand for our Products. Such changes may also impact our business by creating increased volatility and uncertainty in the markets in which we operate. At this time, we cannot predict the ultimate content, timing, or effect of these changes, including any legislative, regulatory and other actions under the new U.S. administration, or estimate the overall impact of any such changes on our business, results of operations and financial condition.

Risks Related to Our Intellectual Property

If we are unable to adequately protect or enforce our intellectual property rights, we may lose valuable assets or incur costly litigation to protect our rights.

Our policy is to actively seek patent protection in the U.S. and to pursue equivalent patent claims in selected foreign countries, thereby seeking patent coverage for novel technologies and compositions of matter that may be commercially important to the development of our business. Granted patents include claims covering the product composition, methods of use and methods of preparation. Our existing patents may not cover future products, additional patents may not be issued and current patents, or patents issued in the future, may not provide meaningful protection or prove to be of commercial benefit.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications may not issue into patents, and any issued patents may not provide sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive technologies or may be held invalid if challenged or circumvented. Patent applications in the U.S. are maintained in confidence for at least 18 months after their filing. Consequently, we cannot be certain that the patent applications we are pursuing will lead to the issuance of any patent or be free from infringement or other claims from other parties. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. laws.

We may have to enforce our intellectual property rights against third parties who infringe our patents and other intellectual property or challenge our patent or trademark applications. For example, in the U.S., putative generics of innovator drug products (including products in which the innovation comprises a new drug delivery method for an existing product, such as the drug delivery market occupied by us) may file Abbreviated New Drug Applications ("ANDA") and, in doing so, certify that their products either do not infringe the innovator's patents or that the innovator's patents are invalid. This often results in litigation between the innovator and the ANDA applicant. This type of litigation is commonly known as "Paragraph IV" litigation in the U.S. On July 27, 2022, we filed a complaint for patent infringement of certain CINVANTI patents against Fresenius Kabi USA, LLC ("Fresenius Kabi") and a related entity in the District of Delaware in response to Fresenius Kabi's ANDA filing seeking approval to manufacture, use or sell a generic version of CINVANTI in the U.S. prior to expiration of the CINVANTI patents. While in December 2024, the District Court found that the Company's CINVANTI patents are valid and would be infringed by Fresenius Kabi's proposed generic product, this decision is currently pending appeal and there is no guarantee that other similar or future litigation will be resolved in our favor. These litigations, of which there are often multiple in process at one time, could result in new or additional generic competition to any of our Products and our product candidates and a potential reduction in product revenue. For example, there is pending litigation relating to the Company's CINVANTI patents against Mylan Pharmaceuticals Inc., and Azurity Pharmaceuticals, Inc. (and its subsidiaries).

We may enter into collaborative agreements that may subject us to obligations that must be fulfilled and require us to manage complex relationships with third parties. In the future, if we are unable to meet our obligations or manage our relationships with our collaborators under these agreements our revenue may decrease. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under

collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration, requiring us to divert management time and resources to such dispute.

Because the patent positions of pharmaceutical and biotechnology companies involve complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to products and processes, including ours, in the U.S., remains uncertain and is dependent on the scope of protection decided on by the patent offices, courts and lawmakers in these countries. The America Invents Act, which was enacted in 2011 and reformed certain patent laws in the U.S., may create additional uncertainty. Patents, if issued, may be challenged, invalidated or circumvented. As more products are commercialized using our proprietary product platforms, or as any product achieves greater commercial success, our patents become more likely to be subject to challenge by potential competitors.

We also rely on trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for such breach. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference proceedings declared by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may not prove successful. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

We may be subject to claims that we have infringed on the intellectual property rights of others, and any litigation could force us to stop developing or selling potential products and could be costly, divert management attention and harm our business.

We must be able to develop products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to the composition of a variety of polymers, specific products, product groups and processing technology, it could be difficult for us to use our technologies or develop products without infringing the proprietary rights of others. Therefore, there is risk that third parties may make claims of infringement against our Products, our product candidates or our technologies. We may not be able to design around the patented technologies or inventions of others, and we may not be able to obtain licenses to use patented technologies on acceptable terms, or at all. If we cannot operate without infringing the proprietary rights of others, we will not be able to develop or commercialize some or all of our product candidates, and consequently will not be able to earn product revenue.

There is considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world. We cannot currently determine the ultimate scope and validity of patents that may be granted to third parties in the future or which patents might be asserted to be infringed by any future manufacture, use or sale of our Products and our product candidates. In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights.

If we are required to defend ourselves in a patent-infringement lawsuit, we could incur substantial costs, and the lawsuit could divert management attention, regardless of the lawsuit's merit or outcome. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to redesign affected products or obtain a license

to continue to manufacture or market the accused product or process and any license required under any such patent may not be made available to us on acceptable terms, if at all. Competitors may sue us as a way of delaying the introduction of our Products and our product candidates. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the U.S. or in countries outside the U.S., or litigation against our partners may be costly and time-consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our Products and our product candidates. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our Products and our product candidates.

Periodically, we review publicly available information regarding the development efforts of others in order to determine whether these efforts may violate our proprietary rights. We occasionally determine that litigation is necessary to enforce our proprietary rights against others. Such litigation can result in substantial expense, regardless of its outcome, and may not be resolved in our favor.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology and 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. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Common Stock

The price of our common stock has been and may continue to be volatile.

The stock markets, in general, and in particular with respect to biotech and life sciences companies, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In addition, the limited trading volume of our stock may contribute to its volatility. Our stock price may be particularly volatile given the stage of our business.

In the past, following periods of volatility in the market price of a particular company’s securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management’s attention and our Company’s resources.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law, our certificate of incorporation and our bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our Board of Directors (the "Board"). These provisions include authorizing the issuance of "blank check" preferred stock without any need for action by stockholders.

In addition, Section 203 of Delaware General Corporation Law, which is applicable to us, may discourage, delay or prevent a change in control of our Company by prohibiting stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us, unless certain approvals are obtained.

Future utilization of net operating loss carryforwards or research and development credit carryforwards may be impaired due to changes in ownership.

We believe our net operating loss and research and development credit carryforwards, and certain other tax attributes, may be subject to limitation under Section 382 of the Internal Revenue Code of 1986 ("IRC"). As a result, our deferred tax assets, and related valuation allowance, have been reduced for the estimated impact of the net operating loss and research and development credit carryforwards that we currently estimate may expire, unused. Utilization of our remaining net operating loss and research and development credit carryforwards may still be subject to substantial annual limitations due to ownership change limitations provided by the IRC and similar state provisions for ownership changes after August 2025, including those that may come in conjunction with future equity financings or market trades by our stockholders. Our Board has adopted a Tax Benefit Preservation Plan, dated August 14, 2025, with Computershare Trust Company, N.A., as rights agent, to act as a deterrent to any person acquiring 4.99% or more of the outstanding shares of our common stock, or any existing 4.99% or greater holder from acquiring any additional shares of our common stock, in each case, without the approval of the Board and thus mitigate the threat that stock ownership changes present to our net operating loss asset.

Actions of activist stockholders could impact the pursuit of our business strategies, cause us to incur substantial costs, divert our management's attention and resources, and adversely affect our business, results of operations, liquidity, financial condition, and the trading price of our common stock.

While we value constructive input from investors and regularly engage in dialogue with our stockholders, and we welcome their views and opinions regarding strategy and performance, we may be subject to actions or proposals from activist stockholders that may not align with our business strategies or the interests of our other stockholders, and the Board and our management are committed to acting in the best interests of all of our stockholders. Accordingly, there is no assurance that the actions taken by the Board and our management in seeking to maintain constructive engagement with certain stockholders will be successful in preventing the occurrence of stockholder activist campaigns.

As previously reported, in February 2023, we entered into a Cooperation Agreement with two of our stockholders, Rubric Capital Management LP and certain of its affiliates and Velan Capital Investment Management LP and certain of its affiliates (collectively, the "Investor Group"), regarding certain changes to the composition of the Board, among other items.

In August 2025, we entered into a Cooperation Agreement with Rubric Capital Management LP, regarding certain changes to the composition of the Board and other related matters.

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with any proxy contest or activist stockholder request or action in the future, we may not be able or willing to respond successfully to the contest, request, or action, which could be significantly disruptive to our business. Even if we are successful, our business, results of operations, liquidity, financial condition, and trading price of our common stock could be adversely affected by any proxy contest or activist stockholder request or action involving us because:

- responding to proxy contests and requests or actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees, and can lead to uncertainty;

- perceived uncertainties as to the future direction of the Company and our business may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners;

- if individuals are elected or appointed to the Board with a specific agenda, it may adversely affect our ability to effectively implement our strategic plan in a timely manner and create additional value for our stockholders; and

- if individuals are elected or appointed to the Board who do not agree with our strategic plan, the ability of the Board to function effectively could be adversely affected.

We cannot predict, and no assurances can be given, as to the outcome or timing of any matters relating to the foregoing actions by activist stockholders and our responses thereto or the ultimate impact on our business, results of operations, liquidity, financial condition, and trading price of our common stock. Any such activist stockholder contests, requests or actions, or the mere public presence of activist stockholders among our stockholder base, could cause the market price of our common stock to experience periods of significant volatility or stagnation.

If we identify a material weakness in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our common stock could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results.

If we cannot conclude that we have effective internal control over our financial reporting, investors could lose confidence in the reliability of our financial statements. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The Nasdaq Capital Market or other regulatory authorities.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the source of gain for our stockholders.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our current and future earnings to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

In the ordinary course of our business, we collect, use, store, and transmit digitally large amounts of confidential, sensitive, proprietary, and personal information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by a dedicated information technology team, which is led by our Chief Financial Officer and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. For example, we conduct vulnerability testing, data recovery testing, security audits, and ongoing risk assessments, including due diligence on and audits of our key technology vendors, and other contractors and suppliers. We also conduct periodic employee training on cyber and information security, among other topics. In addition, we consult with outside advisors and experts, when appropriate to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on the Company's risk environment.

In the last fiscal year, we have not identified risks from known cybersecurity threats, including any prior cybersecurity incidents, that have materially affected us. However, we face certain ongoing cybersecurity threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, "Risk Factors."

Governance

Our Chief Financial Officer, who reports directly to the Chief Executive Officer and has over 15 years of experience managing information technology and cybersecurity matters, is responsible for assessing and managing cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework.

The Board, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is comprised solely of independent directors, has been designated by the Board to oversee cybersecurity risks. The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our Chief Financial Officer. The Board also receives updates from management and the Audit Committee on cybersecurity risks on at least an annual basis.

ITEM 2. PROPERTIES.

We have an operating lease for 52,148 square feet of laboratory and office space in San Diego, California, which expired on December 31, 2025. In October 2021, we entered into a sublease agreement to sublet 23,873 square feet of laboratory and office space in San Diego, California. The space was delivered to the subtenant in March 2022. As a result of the sublease agreement, our one five-year option to renew this lease on expiration applied only with respect to our remaining 28,275 square feet of laboratory and office space.

We have a short-term operating lease for 9,882 square feet of office space in Cary, North Carolina, which was entered into in December 2025 and will expire on February 28, 2026.

In August 2025, we entered into a lease agreement for 16,837 square feet of office space in Cary, North Carolina, with the lease term expected to commence no later than May 25, 2026 ("lease commencement date") and expire 111 months from the lease commencement date, with the option to extend for one additional period of 84 months upon written notice.

ITEM 3. LEGAL PROCEEDINGS.

On June 14, 2022, the Company received a Paragraph IV notice of certification (the "Fresenius Kabi Notice") from Fresenius Kabi advising that Fresenius Kabi had submitted an abbreviated new drug application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture, use or sell a generic version of CINVANTI in the U.S. prior to the expiration of U.S. Patent Nos.: 9,561,229; 9,808,465; 9,974,742; 9,974,793; 9,974,794; 10,500,208; 10,624,850; 10,953,018; and 11,173,118 (the "CINVANTI Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The Fresenius Kabi Notice alleges that the CINVANTI Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Fresenius Kabi's ANDA.

On July 27, 2022, the Company filed a complaint for patent infringement of the CINVANTI Patents against Fresenius Kabi and a related entity in the U.S. District Court for the District of Delaware (the "Court") in response to Fresenius Kabi's ANDA filing. The complaint seeks, among other relief, equitable relief enjoining Fresenius Kabi from infringing the CINVANTI Patents. On May 15, 2024, the Court granted partial summary judgment of infringement for the Company and found no indefiniteness of U.S. Patent Nos. 9,561,229 and 9,974,794. On June 24, 2024, the parties commenced a four-day bench trial centered on Fresenius Kabi's defense of obviousness of claims from U.S. Patent Nos. 9,561,229 and 9,974,794 that cover CINVANTI. Oral argument was held on August 29, 2024.

On December 3, 2024, the Court issued a ruling in the Company's favor. The Court found that the Company's U.S. Patent Nos. 9,561,229 and 9,974,794, which expire in 2035, are valid and would be infringed by Fresenius Kabi's proposed generic product. In view of the decision, the Court ordered that the effective date of any final approval by the FDA of Fresenius Kabi's ANDA shall not be a date earlier than September 18, 2035, the expiration date of each of U.S. Patent Nos. 9,561,229 and 9,974,794. On January 8, 2025, Fresenius Kabi filed notice of appeal to the U.S. Court of Appeals for the Federal Circuit. On September 24, 2025, the briefing was completed, and the Company awaits a date for oral argument. The Company intends to vigorously enforce its intellectual property rights relating to CINVANTI.

On August 4, 2023, the Company received a Notice Letter (the "Mylan August Notice") from Mylan Pharmaceuticals Inc. ("Mylan") advising that Mylan had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of CINVANTI ("Mylan's ANDA for a generic version of CINVANTI") in the U.S. prior to the expiration of the CINVANTI Patents, which are listed in the Orange Book. On September 15, 2023, the Company filed a complaint for patent infringement of the CINVANTI Patents against Mylan in the U.S. District Court for the District of Delaware in response to the filing of Mylan's ANDA for a generic version of CINVANTI. May 6, 2025, the Company announced that it entered into a settlement agreement with Mylan to resolve the ongoing patent litigation in the U.S. District Court for the District of Delaware related to Mylan's ANDA for a generic version of CINVANTI. Pursuant to the terms of the settlement agreement, the Company has granted Mylan a license under the Orange Book-listed patents for CINVANTI to market a generic version of CINVANTI in the United States beginning June 1, 2032, or earlier under certain customary circumstances. In connection with the settlement, on May 6, 2025, the Court granted the Stipulation and Order of Dismissal with the U.S. District Court for the District of Delaware requesting that the Court dismiss the pending litigation between the parties.

On December 16, 2023, the Company received a Notice Letter (the "Mylan December Notice") from Mylan advising that Mylan had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of APONVIE in the U.S. ("Mylan's ANDA for a generic version of APONVIE") prior to the expiration of U.S. Patent Nos.: 9,561,229; 9,808,465; 9,974,742; 9,974,793; 9,974,794; 10,500,208; 10,624,850; 10,953,018; 11,173,118; and 11,744,800 (the "APONVIE Patents"), which are listed in the Orange Book. On January 11, 2024, the Company filed a complaint for patent infringement of the APONVIE Patents against Mylan in the U.S. District Court for the District of Delaware in response to Mylan filing its ANDA for a generic version of APONVIE. On May 6, 2025, the Company announced that it entered into a settlement agreement with Mylan to resolve the ongoing

patent litigation in the U.S. District Court for the District of Delaware related to Mylan's ANDA for a generic version of APONVIE. Pursuant to the terms of the settlement agreement, the Company has granted Mylan a license under the Orange Book-listed patents for APONVIE to market a generic version of APONVIE in the United States beginning June 1, 2032, or earlier under certain customary circumstances. In connection with the settlement, on May 6, 2025, the Court granted the Stipulation and Order of Dismissal with the U.S. District Court for the District of Delaware requesting that the Court dismiss the pending litigation between the parties.

On December 11, 2023, the Company received a Paragraph IV notice of certification (the "Slayback Notice") from Slayback Pharma LLC ("Slayback") (now owned by Azurity Pharmaceuticals, Inc. ("Azurity")) advising that Slayback had submitted a new drug application ("NDA") under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act to the FDA seeking approval to manufacture, use or sell a generic version of CINVANTI in the U.S. ("Slayback's NDA") prior to the expiration of the patents listed in the Orange Book. The Slayback Notice alleges that the CINVANTI Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Slayback's NDA. On January 24, 2024, the Company filed a complaint for patent infringement of the CINVANTI Patents against Slayback and a related entity in the U.S. District Court for the District of New Jersey in response to Slayback's NDA filing. The complaint seeks, among other relief, equitable relief enjoining Slayback from infringing those patents. On July 2, 2024, the U.S. District Court for the District of New Jersey granted Slayback's motion to transfer this matter to the U.S. District Court for the District of Delaware. On December 12, 2024, the Company filed a complaint against Slayback, Azurity, and related entities in the U.S. District Court for District of Delaware for patent infringement of U.S. Patent Nos. 12,115,254 and 12,115,255. On May 23, 2025, the Company filed an amended complaint against Slayback, Azurity and related entities adding an allegation of patent infringement of U.S. Patent No. 12,290,520. On September 16, 2025, the parties entered into a stipulation (Case No. 24-1363, D.I. 119) limiting the issues for trial. On November 17, 2025, the parties commenced a two-day bench trial centered on Azurity's §112 defenses of claims from U.S. Patent Nos. 12,115,255 and 12,290,520 that cover CINVANTI. On February 6, 2026, the post-trial briefing was completed, and the Company awaits a date for oral argument. The Company intends to vigorously enforce its intellectual property rights relating to CINVANTI. As a result of our initial complaint for patent infringement, the FDA may not approve Slayback's NDA until the earlier of June 12, 2026 or resolution of the litigation.

On February 28, 2025, Azurity, Azurity Pharma India LLP, and Slayback requested Post-Grant Review ("PGR") of U.S. Patent Nos. 12,115,254 and 12,115,255 in PGR2025-00035 and PGR2025-00036, respectively. On April 14, 2025, the Petitions were accorded a filing date. On June 16, 2025, the Company filed a brief requesting discretionary denial of the Petitions in PGR2025-00035 and PGR2025-00036. On July 14, 2025, the Company filed its Patent Owner Preliminary Response. On August 14, 2025, the Patent Trial and Appeal Board discretionarily denied institution of Azurity's PGRs.

On February 7, 2025, the Company received a Notice Letter (the "Qilu Notice") from Qilu Pharmaceutical (Hainan) Co., Ltd and Qilu Pharma, Inc. ("Qilu") advising that Qilu had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of APONVIE in the U.S. ("Qilu's ANDA for a generic version of APONVIE") prior to the expiration of U.S. Patent Nos.: 9,561,229; 9,808,465; 9,974,742; 9,974,793; 9,974,794; 10,500,208; 10,624,850; 10,953,018; 11,173,118; 11,744,800, 11,878,074, 12,115,254, and 12,115,255 (the "Noticed APONVIE Patents"), which are listed in the Orange Book. On March 21, 2025, the Company filed a complaint for patent infringement of the Noticed APONVIE Patents against Qilu in the U.S. District Court for the District of Delaware in response to Qilu's ANDA for a generic version of APONVIE.

On June 11, 2025, the Company received a Notice Letter (the "Qilu CINVANTI Notice") from Qilu advising that Qilu had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of CINVANTI in the U.S. ("Qilu's ANDA for a generic version of CINVANTI") prior to the expiration of U.S. Patent Nos.: 9,561,229; 9,808,465; 9,974,742; 9,974,793; 9,974,794; 10,500,208; 10,624,850; 10,953,018; 11,173,118; 11,744,800; 12,115,254; 12,115,255; and 12,290,520 (the "Noticed CINVANTI Patents"), which are listed in the

Orange Book for CINVANTI. On July 3, 2025, the Company filed a complaint for patent infringement of the Noticed CINVANTI Patents against Qilu in the U.S. District Court for the District of Delaware in response to Qilu's ANDA for a generic version of CINVANTI.

On July 15, 2025, the Qilu CINVANTI and APONVIE litigations were consolidated. The Company entered into a settlement agreement with Qilu to resolve the ongoing patent litigation in the U.S. District Court for the District of Delaware related to Qilu's ANDAs for generic versions of CINVANTI and APONVIE. In connection with the settlement, on November 6, 2025, the Court granted the Stipulation and Order of Dismissal with the U.S. District Court for the District of Delaware requesting that the Court dismiss the pending litigation between the parties.

On November 19, 2025, the Company received a Paragraph IV notice of certification (the "Baxter Notice") from Baxter Healthcare Corporation ("Baxter") advising that Baxter had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of CINVANTI ("Baxter's ANDA for a generic version of CINVANTI") in the U.S. prior to the expiration of the Noticed CINVANTI Patents, which are listed in the Orange Book. The Baxter Notice alleges that the Noticed CINVANTI patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Baxter's ANDA for a generic version of CINVANTI. On December 23, 2025, the Company filed a complaint for patent infringement of the Noticed CINVANTI Patents against Baxter and a related entity in the U.S. District Court for the District of Delaware in response to the filing of Baxter's ANDA for a generic version of CINVANTI. The complaint seeks, among other relief, equitable relief enjoining Baxter from infringing the Noticed CINVANTI Patents. The Company intends to vigorously enforce its intellectual property rights relating to CINVANTI. As a result of our complaint for patent infringement, the FDA may not approve Baxter's ANDA for a generic version of CINVANTI until the earlier of May 19, 2028 or resolution of the litigation.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Information About Our Common Stock

Shares of our common stock are traded on The Nasdaq Capital Market, under the symbol "HRTX."

Stockholders

As of February 10, 2026, there were 67 holders of record of our common stock, which does not include beneficial owners of stock held in street name (i.e., through a brokerage firm, bank, broker-dealer, trust or other similar organization).

Dividend Policy

We have never paid dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

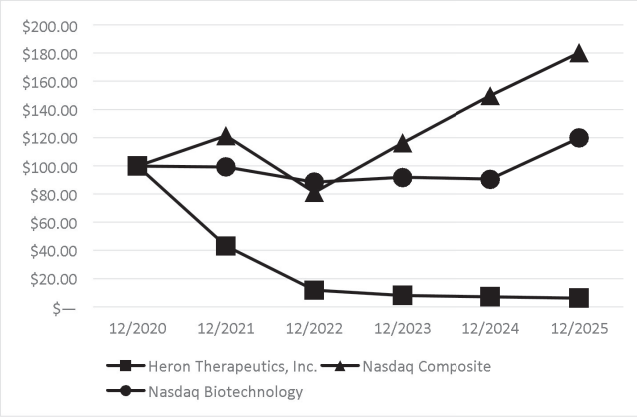
None.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Performance Graph
Cumulative Total Return

The following graph compares the relative performance of our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. This graph covers the period from December 31, 2020 through December 31, 2025 and assumes that $100 was invested on December 31, 2020 in our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index with the reinvestment of any dividends.



	December 31,					
	2020	2021	2022	2023	2024	2025
Heron Therapeutics, Inc.....	$ 100.00	$ 43.14	$ 11.81	$ 8.03	$ 7.23	$ 6.14
Nasdaq Composite Index.....	100.00	121.39	81.21	116.47	149.83	180.33
Nasdaq Biotechnology Index...	100.00	99.37	88.53	91.84	90.58	119.92

The graph is not, and is not intended to be, indicative of future performance of our common stock.

This performance graph shall not be deemed "filed" with the SEC or subject to the liabilities of Section 18 of the Exchange Act, and should not be deemed incorporated by reference into any of our prior or subsequent filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

ITEM 6. [RESERVED].

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read together with our audited financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. You should review the sections entitled "Forward-Looking Statements" and "Risk Factors" in this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Introduction

Management's discussion and analysis of financial condition and results of operations is provided as a supplement to the consolidated financial statements and notes, included in Item 8 of this Annual Report on Form 10-K to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. Our discussion is organized as follows:

- *Overview.* This section provides a general description of our business and operating expenses, as well as other matters that we believe are important to understanding our results of operations and financial condition and in anticipating future trends.

- *Critical accounting estimates.* This section contains a discussion of the accounting estimates that require a significant level of estimation uncertainty, and changes in which are reasonably likely to have a material effect on our financial condition or results of operations. In addition, all of our significant accounting policies are summarized in Note 2 to the consolidated financial statements included in Item 8 of this Annual Report on Form 10-K.

- *Results of operations.* This section provides an analysis of our results of operations presented in the accompanying consolidated statements of operations and comprehensive loss by comparing the results for the year ended December 31, 2025 to the results for the year ended December 31, 2024.

- *Liquidity and capital resources.* This section provides a discussion of our financial condition and liquidity, an analysis of our cash flows for the years ended December 31, 2025 and 2024, and a discussion of our outstanding commitments and contingencies that existed as of December 31, 2025.

Overview

We are a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard of care for acute care and oncology patients.

ZYNRELEF® (bupivacaine and meloxicam) extended-release solution ("ZYNRELEF") is approved in the United States ("U.S.") for the management of postoperative pain. APONVIE® (aprepitant) injectable emulsion ("APONVIE") is approved in the U.S. for the prevention of postoperative nausea and vomiting. CINVANTI® (aprepitant) injectable emulsion ("CINVANTI") and SUSTOL® (granisetron) extended-release injection ("SUSTOL") are both approved in the U.S. for the prevention of chemotherapy-induced nausea and vomiting.

Material Trends and Developments

SUSTOL

We intend to wind down commercialization of SUSTOL over the next 12 months while we evaluate potential product updates. Subject to development progress, manufacturing readiness, and regulatory feedback, we may consider reintroducing SUSTOL as early as late 2027. During the wind down, we will continue to support customers

and manage inventory responsibly, and we expect one-time transition costs, which we will quantify as plans are finalized.

Impact of Global Business, Political and Macroeconomic Conditions

Uncertainty in the political and macroeconomic environments presents significant risks to our business. We are subject to continuing risks and uncertainties, including increasing financial market volatility and uncertainty, inflation, interest rate fluctuations, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, natural or man-made disasters, including severe weather, epidemics, pandemics, cyberattacks, acts of war or terrorism, armed conflict, or global pandemics. We closely monitor the impacts of these factors on all aspects of our business, including the impacts on our clinical trial patients, employees, partners, suppliers, and vendors. The ultimate impact of global economic conditions on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period of time. As a result, we are subject to continuing risks and uncertainties and continue to closely monitor the impact of the current conditions on our business. For more information regarding these risks and uncertainties, see the section titled "Risk Factors" in this Annual Report on Form 10-K.

Crosslink Co-Promotion Agreement

On January 5, 2024, we entered into a five-year co-promotion agreement with Crosslink Network to be the lead partner in the United States to expand the promotion of ZYNRELEF for orthopedic indications. Under the terms of the agreement, Crosslink Network is compensated on a fixed-fee per vial basis, based on growth over a pre-determined baseline period.

Net Product Sales

Net product sales include revenue recognized for sales of ZYNRELEF, APONVIE, CINVANTI, and SUSTOL (collectively, our "Products") to a limited number of specialty distributors and full line wholesalers (collectively, our "customers"), less applicable sales allowances. The revenues we generate are dependent upon and subject to several factors, including those discussed in the "Risk Factors" section of this Annual Report on Form 10-K. Refer to the "Critical Accounting Estimates" section of this Annual Report on Form 10-K for further details on our revenue recognition policy.

Cost of Product Sales

Cost of product sales relates to the costs to produce, package and deliver our Products to our customers. These costs include raw materials, labor, manufacturing and quality control overhead, and depreciation of equipment, as well as shipping and distribution costs. The costs to produce, package and deliver our Products are dependent upon and subject to several factors as discussed in the "Risk Factors" section of this Annual Report on Form 10-K. See the "Critical Accounting Estimates" section of this Annual Report on Form 10-K for further details on our inventory policy.

Research and Development Expense

All costs of research and development are expensed in the period incurred. Research and development expense primarily consists of salaries, stock-based compensation expense and other related costs for personnel in clinical and preclinical development, regulatory, and quality. Other research and development expense includes professional fees paid to outside service providers and consultants, facilities costs and materials used in the clinical and preclinical trials and research and development.

General and Administrative Expense

General and administrative expense primarily consists of salaries, stock-based compensation expense and other related costs for personnel in executive, finance and accounting, information technology, legal, human resource, manufacturing and medical affairs functions. Other general and administrative expense includes professional fees for legal, investor relations, accounting and other general corporate purposes, facility costs and insurance not otherwise included in research and development expense.

Sales and Marketing Expense

Sales and marketing expense primarily consists of salaries and related costs for personnel, stock-based compensation expense and other related costs for sales operations, marketing and market access. Other sales and marketing costs include professional fees and commercialization costs related to our Products.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest expense, income earned on our cash, cash equivalents and short-term investments, the amortization of debt issuance costs and debt discount related to our 2026 Convertible Notes, 2031 Convertible Notes and our Working Capital Facility Agreement, and write-off of property and equipment.

We may be able to control the timing and extent of the operating expenses, but some expenses may be incurred without regard to our actions due to contractual commitments. Our expectations are subject to various risks and assumptions, including but not limited to those listed under the section entitled "Forward-Looking Statements" and "Risk Factors" in this Annual Report on Form 10-K.

Critical Accounting Estimates

A summary of the significant accounting policies is provided in Note 2 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K.

The discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis, including those related to revenue recognition, investments, inventory and the related reserves, accrued clinical and manufacturing liabilities, income taxes, stock-based compensation and accounting for debt and equity transactions. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Management considers an accounting estimate to be critical if it requires a significant level of estimation uncertainty, and changes in the estimate are reasonably likely to have a material effect on our financial condition or results of operations.

We believe the following critical accounting estimates describe the most significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Revenue is recognized in accordance with the Financial Accounting Standards Board Accounting Standards Codification Topic 606, Revenue from Contracts with Customers ("Topic 606"). Topic 606 is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services.

Product Sales

Our Products are distributed in the U.S. through a limited number of customers that resell to healthcare providers and hospitals, the end users of our Products.

Revenue is recognized in an amount that reflects the consideration we expect to receive in exchange for our Products. To determine revenue recognition for contracts with customers within the scope of Topic 606, we perform the following 5 steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations of the contract(s); (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract(s); and (v) recognize revenue when (or as) we satisfy the performance obligations. We recognize

revenue from product sales when there is a transfer of control of the product to our customers. We typically determine transfer of control based on when the product is delivered, and title passes to our customers.

Product Sales Allowances

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. Such variable consideration includes estimates that take into consideration the terms of our agreements with customers, historical product returns, rebates or discounts taken, the shelf life of the product and specific known market events, such as competitive pricing and new product introductions. If actual future results vary from our estimates, we may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

We believe our estimated allowances for distributor fees, group purchasing organization ("GPO") rebates and administrative fees, Medicaid rebates and prompt pay discounts do not require a high degree of judgment because the amounts are settled within a relatively short period of time.

We believe our estimated allowance for product returns and GPO discounts requires a high degree of judgment and is subject to change based on our experience and certain quantitative and qualitative factors. We allow the majority of our customers to return product for credit beginning three months prior to the product expiration date and up to 12 months after the product expiration date. As such, there may be a significant period of time between the time the product is shipped and the time the credit is issued on returned product. We estimate anticipated GPO discounts based on the applicable contractual terms. We regularly monitor our estimates and record adjustments when trends, contract terms or other significant events indicate that a change in estimates is appropriate. To date, our estimates have not differed materially from actuals. However, subsequent changes in estimates may result in a material change to our product sales allowances, which could materially affect our results of operations and financial condition.

Investments

We invest in various types of securities, including U.S. treasury bills and government agency obligations, corporate debt securities and commercial paper. These securities have been initially valued at the transaction price and subsequently valued utilizing a third-party to assess the fair value using inputs other than quoted prices that are observable either directly or indirectly, such as yield curve, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, broker and dealer quotes, as well as other relevant economic measures. We perform certain procedures to corroborate the fair value of these holdings, and in the process, we apply judgment and estimates that if changed, could significantly affect our consolidated balance sheets. To date, our estimates have not differed materially from actual values. However, subsequent changes in estimates may result in a material change to the value of our cash equivalents and short-term investments, which could materially affect our results of operations and financial condition.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value on a first-in, first-out ("FIFO"), basis. We periodically analyze our inventory levels and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory quantities that are in excess of expected sales requirements as cost of product sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as cost of product sales.

Accrued Clinical and Manufacturing Liabilities

We estimate certain costs and expenses and accrue for these liabilities as part of our process of preparing financial statements. Examples of areas in which subjective judgment may be required include, among other things, costs associated with services provided by contract organizations for manufacturing of our Products. We accrue for costs incurred as the services are being provided by monitoring the status of the services provided, and the invoices received from our external service providers. Revisions are recorded to research and development expense or inventory in the period in which the facts that give rise to the revision become known. Historically, revisions have

not resulted in material changes to research and development expense or inventory. However, a modification could result in a material charge to our results of operations.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain deferred tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes. As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes for each of the jurisdictions in which we operate. This process involves estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and financial statement purposes. On December 31, 2025, we established a valuation allowance to offset our deferred tax assets due to the uncertainty of realizing future tax benefits from our net operating loss carryforwards and other deferred tax assets. To date, our estimates have not materially changed. However, subsequent changes in estimates may result in a significant change to our deferred tax assets and liabilities, which could materially affect our results of operations and financial condition.

Stock-based Compensation

We estimate the fair value of stock options granted using the Black-Scholes option pricing model and for market-based stock option grants using the Monte Carlo simulation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option pricing model requires the input of subjective assumptions, including each option's expected life and price volatility of the underlying stock. Expected volatility is based on our historical stock price volatility. The expected life of employee stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. To date, our assumptions used in our calculation of stock-based compensation expense has not significantly changed. However, subsequent changes in our assumptions could impact our stock-based compensation expense, which could materially affect our net loss and net loss per share.

Accounting for debt and equity transactions

We evaluate our debt and equity transactions in accordance with ASC Topic 470, *Debt,* ASC 480-10, Distinguishing Liabilities from Equity and ASC Subtopic 815-40, Contracts in Entity's Own Equity ("ASC 815-40").

Through our evaluation of our debt transactions, we consider whether the transaction represents a troubled debt restructuring, an extinguishment or modification. Furthermore, consider whether the transaction includes embedded derivatives and whether any embedded derivatives require bifurcation. Changes in our judgments and conclusions could impact the effective interest expense and loss recognized on debt extinguishment, which could materially affect our net loss and net loss per share.

During the year ended December 31, 2025, we issued Series A convertible preferred stock, which required evaluation of classification of the Series A convertible preferred stock. Changes in our judgments and conclusions could impact the classification and carrying value of the Series A convertible preferred stock, which could affect our net loss and net loss per share.

Recent Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Results of Operations

The following discussion and analysis of our Results of Operations and Liquidity and Capital Resources includes a comparison of the year ended December 31, 2025 to the year ended December 31, 2024. A similar discussion and analysis that compares the year ended December 31, 2024 to the year ended December 31, 2023 can be found in Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Comparison of Results of Operations

	Years Ended December 31,			
($ in thousands)	**2025**	**% of Sales**	**2024**	**% of Sales**
Net product sales	$ 154,904		$ 144,285	
Cost of product sales	41,347	26.7%	38,648	26.8%
Gross Profit	$ 113,557		$ 105,637	
Operating expenses:				
Research and development	12,429	8.0%	16,683	11.6%
General and administrative	54,605	35.3%	53,397	37.0%
Sales and marketing	49,061	31.7%	47,085	32.6%
Loss from operations	$ (2,538)	(1.6%)	$ (11,528)	(8.0%)

Net Product Sales

	Years Ended December 31,	
	2024	**2023**
Acute Care Net Product Sales	$ 49,643	$ 30,064
Oncology Net Product Sales	$ 105,261	$ 114,221
Total Net Product Sales	**$ 154,904**	**$ 144,285**

	2025 vs. 2024
Acute Care Growth	65.1%
Oncology Growth	(7.8%)
Total Net Product Sales Growth	**7.4%**

Total acute care net product sales increased 65.1% during the year ended December 31, 2025, as compared to the prior year, primarily driven by an increase in the units sold as a result of increase in market share and new customers for both ZYNRELEF and APONVIE.

Total oncology net product sales decreased 7.8% during the year ended December 31, 2025, as compared to the prior year, primarily driven by an increase in gross to net adjustments to maintain market share of 23.0% and a decrease in SUSTOL units sold of 6.7%, offset by an increase in CINVANTI units sold of 21.8%.

Cost of Product Sales

Cost of product sales increased 7.0% or $2.7 million during the year ended December 31, 2025, as compared to the prior year and as a percentage of sales, decreased 0.1% during the same period. The increase in cost of product sales during the year ended December 31, 2025 was primarily driven by an increase in the units sold and product mix, which contributed $0.5 million to the increase in cost of product sales and an increase in inventory reserves and write-offs recorded of $2.1 million in the year ended December 31, 2025.

Research and Development Expense

Research and development expense consisted of the following (in thousands):

	December 31,	
	2025	2024
ZYNRELEF-related costs	$ 6,305	$ 6,424
CINVANTI-related costs	352	1,441
SUSTOL-related costs	95	428
APONVIE-related costs	2	405
Personnel costs and other expenses	4,642	6,129
Stock-based compensation expense	1,033	1,856
Total research and development expense	$ 12,429	$ 16,683

Research and development expense decreased 25.5% or $4.3 million during the year ended December 31, 2025, compared to the prior year and as a percentage of sales, decreased 3.6% during the same period. The decrease is primarily due to decreased personnel and related costs of $2.2 million due to terminations during the year ended December 31, 2024. The decrease is also due to $1.7 million more in asset write-offs in the year ended December 31, 2024 than in the year ended December 31, 2025.

General and Administrative Expense

General and administrative expense increased 2.3% or $1.2 million during the year ended December 31, 2025, compared to the prior year and as a percentage of sales, decreased 1.7% during the same period. The increase in general and administrative expenses during the year ended December 31, 2025 was due to a $0.9 million increase in expenses due to timing and an increase of $0.3 million in legal expenses primarily due to timing of litigation.

Sales and Marketing Expense

Sales and marketing expense increased 4.2% or $2.0 million during the year ended December 31, 2025, compared to the prior year and as a percentage of sales, decreased 0.9% during the same period. The increase in sales and marketing expense was primarily due to an increase in marketing costs of $2.7 million, primarily related to the promotion of ZYNRELEF. This increase was offset by a net decrease in personnel and related costs of $0.6 million as a result of an increase in headcount during the year ended December 31, 2025 contributing $1.3 million in expense, offset by a decrease in stock compensation expense of $1.9 million primarily due to one-time stock compensation expense in the year ended December 31, 2024.

Other (Expense) Income, Net

Other (expense) income, net increased $15.6 million during the year ended December 31, 2025, compared to the prior year, primarily due to the loss on debt extinguishment of $11.3 million, an increase in interest expense associated with our debt agreements, of $3.6 million, and a decrease in interest income of $0.7 million as a result of lower interest rates.

Liquidity and Capital Resources

As of December 31, 2025, we had cash, cash equivalents and short-term investments of $46.6 million. Based on our current operating plan and projections, management believes that the Company’s existing cash, cash equivalents and short-term investments will be sufficient to meet the Company’s anticipated cash requirements for a period of at least one year from the date this Annual Report on Form 10-K is filed with the U.S. Securities and Exchange Commission.

Our net loss for the year ended December 31, 2025 was $20.2 million, or $0.12 per share, compared to a net loss of $13.6 million, or $0.09 per share, for the same period in 2024.

Our net cash used in operating activities for the year ended December 31, 2025 was $27.6 million, compared to $22.5 million for the same period in 2024. The increase in net cash used in operating activities was primarily due

to changes in working capital, specifically, purchases of inventory, accounts receivable due to the timing of collections and accounts payable and accrued expenses due to the timing of payments.

Our net cash provided by investing activities for the year ended December 31, 2025 was $16.0 million, compared to $18.7 million for the same period in 2024. The decrease in cash provided by investing activities was primarily due to net maturities of short-term investments of $16.2 million for the year ended December 31, 2025, compared to net maturities of short-term investments of $20.4 million for the same period in 2024, offset by a decrease in purchases of property and equipment of $1.4 million during the year ended December 31, 2025 as compared to the prior year.

Our net cash provided by financing activities for the year ended December 31, 2025 was $14.4 million, compared to $0.9 million for the same period in 2024. The increase in cash provided by financing activities was primarily due to net proceeds of $13.4 million received from debt and equity financings completed in the third quarter of 2025. The increase in net cash provided by financing activities for the year ended December 31, 2025 was also a result of an increase in proceeds from transactions under the Employee Stock Purchase Plan and the equity incentive plan of $0.1 million.

Historically, we have financed our operations, including technology and product research and development, primarily through sales of our common stock, product sales and debt financings.

Material Cash Requirements

As of December 31, 2025, $111.2 million in aggregate principal amount, including accumulated paid-in-kind interest, under the Working Capital Facility Agreement were outstanding (see Note 8 to the Consolidated Financial Statements included in this Annual Report on Form 10-K). The Working Capital Facility agreement matures September 1, 2030.

As of December 31, 2025, $35.9 million aggregate principal amount, including accumulated paid-in-kind interest, for the 2031 Convertible Notes was outstanding (see Note 8 to the Consolidated Financial Statements included in this Annual Report on Form 10-K). The 2031 Convertible Notes mature on March 1, 2031, unless earlier converted, redeemed or repurchased.

On December 31, 2025, purchase obligations primarily consisted of non-cancellable commitments with third-party manufacturers in connection with the manufacturing of our Products. Total purchase obligations of $19.0 million were not included in our consolidated financial statements for the year ended December 31, 2025, all of which are due within one year. We intend to use our current financial resources to fund our commitments under these purchase obligations.

As of December 31, 2025, we have a short-term operating lease for 9,882 square feet of office space in Cary, North Carolina, which was entered into in December 2025 and will expire on February 28, 2026. In August 2025, we entered into a lease agreement for 16,837 square feet of office space in Cary, North Carolina, with the lease term expected to commence no later than May 25, 2026 ("lease commencement date") and expire 111 months from the lease commencement date, with the option to extend for one additional period of 84 months upon written notice.

We enter into agreements with contract manufacturing organizations for the manufacture and supply of commercial materials and drug product. In some of our agreements with contract manufacturing organizations, we are required to meet minimum purchase obligations. Under certain of these agreements, we may be subject to penalties in the event that we prematurely terminate these agreements. At this time, due to the variability associated with contract manufacturing agreements, we are unable to estimate with certainty the future costs we will incur. We intend to use our current financial resources to fund our obligations under these commitments.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value due to changes in interest rates and other market factors, as well as the increase or decrease in any realized gains and losses. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. We generally have the ability to hold our fixed-income investments to maturity and, therefore, do not expect that our operating results, financial condition or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not believe that we have material exposure to interest rate risk arising from our investments. We have not realized any significant losses from our investments. We do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities.

Foreign Currency Exchange Rate Risk

Most of our revenues and expenses are denominated in the U.S. Dollar. We also incur transactions in foreign currency, principally denominated in Euros, primarily related to contract manufacturing, and we expect to continue to do so. Our limited foreign currency exposure is to fluctuations in the Euro. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future. We have not engaged in foreign currency hedging to date. Foreign currency gains or losses are included in the line items to which they relate in the Consolidated Statements of Operations and Comprehensive Loss.

Inflation Risk

Inflation generally impacts us by potentially increasing our operating expenses, including cost of product sales. We do not believe that inflation has had a material impact on our business or results of operations during the periods for which the consolidated financial statements are presented in this report. Significant adverse changes in inflation could negatively impact our future results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Heron Therapeutics, Inc.

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of Heron Therapeutics, Inc. and subsidiaries (the “Company”) as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, stockholders’ equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company’s internal control over financial reporting as of December 31, 2025, based on criteria established in *2013 Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in *2013 Internal Control—Integrated Framework* issued by the COSO.

Basis for Opinion

The Company’s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management Report on Internal Control Over Financial Reporting*. Our responsibility is to express an opinion on the Company’s consolidated financial statements and an opinion on the entity’s internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

An entity's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. An entity's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the entity; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and directors of the entity; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements; and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Allowance for Product Returns

Description of the Matter

As discussed in Notes 2 and 5 to the consolidated financial statements, the Company earns its revenue through the sale of its products, CINVANTI, SUSTOL, ZYNRELEF, and APONVIE, in the U.S. through a limited number of specialty distributors and full line wholesalers. The Company's net product sales totaled $154.9 million for the year ended December 31, 2025. The amount of revenue recognized is net of product sales allowances for product returns, distributor fees, group purchasing organization (GPO) discounts and rebates, GPO administrative fees, Medicare rebates, and prompt pay discounts. As of December 31, 2025, the Company's liability related to product sales allowances was $46.0 million. The allowances are recorded in the same period that the related revenue is recognized and create variability in the consideration that the Company expects to receive. Management's estimated allowance for product returns requires a high degree of judgment and is subject to change based on various quantitative and qualitative factors due to the significant period of time that may occur between the time the product is shipped and the time the product may be returned. Accordingly, extensive audit effort and a high degree of auditor judgment were needed to evaluate management's estimates and assumptions used in the determination of the allowance for product returns. Therefore, we identified management's allowance for product returns as a critical audit matter.

How We Addressed the Matter in Our Audit

To address this matter, through our integrated audit approach, we performed both control testing as well as substantive audit procedures. We obtained an understanding of, evaluated the design and tested the operating effectiveness of management's controls over the Company's processes related to recording the allowance for product returns, including testing management's quarterly control to perform a hindsight analysis and review historical return rates.

We also evaluated the significant accounting policies relating to product returns, as well as management's application of the policies, for appropriateness and reasonableness. As part of our substantive testing procedures, we performed the following procedures:

- Obtained and read contract source documents to understand the key terms related to the Company's contracts.
- Tested the reasonableness of management's assumptions in calculating the allowance for product returns by comparing the assumptions to historical data, peer group information, and, where available, subsequent product returns.
- Evaluated whether the selected estimates were applied consistently across similar arrangements.
- Selected a sample of transactions used in management's assessment of its allowance for product returns analysis to test the completeness and accuracy of the data used in the analysis.

Additionally, we tested the mathematical accuracy of management's calculation of revenue, net of product sales allowances, including product returns, and the associated timing of revenue recognition, in the consolidated financial statements.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2006.

Orlando, Florida

February 26, 2026

PCAOB ID Number 100

HERON THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value and share amounts)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,647	$ 25,802
Short-term investments	17,984	33,481
Accounts receivable, net	89,587	78,881
Inventory, net	92,746	53,160
Prepaid expenses and other current assets	9,102	17,690
Total current assets	238,066	209,014
Property and equipment, net	12,403	14,863
Right-of-use lease assets	—	2,787
Other assets	5,408	6,483
Total assets	$ 255,877	$ 233,147
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 8,994	$ 11,709
Accrued clinical and manufacturing liabilities	26,597	25,402
Accrued payroll and employee liabilities	9,270	9,554
Other accrued liabilities	51,237	41,755
Current lease liabilities	—	3,037
Total current liabilities	96,098	91,457
Non-current notes payable, net	107,899	25,026
Non-current convertible notes payable, net	32,739	149,700
Other non-current liabilities	4,808	615
Total liabilities	241,544	266,798
Commitments and contingencies (see Note 6)		
Stockholders' deficit:		
Common stock, $0.01 par value: 400,000,000 shares authorized; 188,314,430 shares issued and outstanding at December 31, 2025 and 152,127,878 shares issued and outstanding at December 31, 2024	1,883	1,521
Series A convertible preferred stock, $0.01 par value: 2,500,000 shares authorized; 70,012 shares issued and outstanding at December 31, 2025 and no shares issued and outstanding at December 31, 2024	1,050	—
Additional paid-in capital	1,951,185	1,884,409
Accumulated other comprehensive income	4	13
Accumulated deficit	(1,939,789)	(1,919,594)
Total stockholders' equity (deficit)	14,333	(33,651)
Total liabilities and stockholders' equity (deficit)	$ 255,877	$ 233,147

See accompanying Notes to Consolidated Financial Statements.

HERON THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Years Ended December 31,		
	2025	2024	2023
Net product sales	$ 154,904	$ 144,285	$ 127,044
Cost of product sales	41,347	38,648	65,105
Gross profit	113,557	105,637	61,939
Operating expenses:			
Research and development	12,429	16,683	39,133
General and administrative	54,605	53,397	65,778
Sales and marketing	49,061	47,085	67,643
Total operating expenses	116,095	117,165	172,554
Loss from operations	(2,538)	(11,528)	(110,615)
Other (expense) income, net:			
Interest income	1,948	3,550	3,364
Interest expense	(9,605)	(6,032)	(3,868)
Loss on debt extinguishment	(11,339)	—	—
Other income	1,339	430	560
Total other (expense) income, net	(17,657)	(2,052)	56
Net loss	(20,195)	(13,580)	(110,559)
Other comprehensive (loss) income:			
Unrealized (losses) gains on short-term investments	(9)	-	32
Comprehensive loss	$ (20,204)	$ (13,580)	$ (110,527)
Basic and diluted net loss per share	$ (0.12)	$ (0.09)	$ (0.80)
Shares used in computing basic and diluted net loss per share	166,707	152,449	138,135

See accompanying Notes to Consolidated Financial Statements.

HERON THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Common Stock		Series A Convertible Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity (Deficit)
Balance, December 31, 2022	119,155	$ 1,191	—	$ —	$1,807,855	$ (19)	$ (1,795,455)	$ 13,572
Issuance of common stock under Employee Stock Purchase Plan	717	7	—	—	897	—	—	904
Issuance of common stock under equity incentive plan	1,130	11	—	—	(914)	—	—	(903)
Issuance of common stock in a private placement	20,735	208	—	—	29,547	—	—	29,755
Issuance of common stock on exercise of pre-funded warrants	8,548	86	—	—	(85)	—	—	1
Issuance of warrant in debt financing	—	—	—	—	371	—	—	371
Stock-based compensation expense	—	—	—	—	32,854	—	—	32,854
Net loss	—	—	—	—	—	—	(110,559)	(110,559)
Net unrealized gain on short-term investments	—	—	—	—	—	32	—	32
Comprehensive loss	—	—	—	—	—	—	—	(110,527)
Balance, December 31, 2023	150,285	$ 1,503	—	$ —	$1,870,525	$ 13	$ (1,906,014)	$ (33,973)
Issuance of common stock under Employee Stock Purchase Plan	640	6	—	—	631	—	—	637
Issuance of common stock under equity incentive plan	1,203	12	—	—	291	—	—	303
Stock-based compensation expense	—	—	—	—	12,962	—	—	12,962
Net loss	—	—	—	—	—	—	(13,580)	(13,580)
Comprehensive loss	—	—	—	—	—	—	—	(13,580)
Balance, December 31, 2024	152,128	$ 1,521	—	$ —	$1,884,409	$ 13	$ (1,919,594)	$ (33,651)
Issuance of common stock under Employee Stock Purchase Plan	658	7	—	—	846	—	—	853
Issuance of common stock under equity incentive plan	1,095	11	—	—	149	—	—	160
Issuance of common stock in settlement of 2026 Convertible Notes	16,667	167	—	—	30,500	—	—	30,667
Issuance of common stock in a private placement equity offering	13,225	132	—	—	18,175	—	—	18,307
Issuance of Series A convertible preferred stock in a private placement equity offering	—	—	524	7,862	—	—	—	7,862
Conversion of Series A convertible preferred stock to common stock	4,541	45	(454)	(6,812)	6,767	—	—	—
Stock-based compensation expense	—	—	—	—	10,339	—	—	10,339
Net loss	—	—	—	—	—	—	(20,195)	(20,195)
Net unrealized loss on short-term investments	—	—	—	—	—	(9)	—	(9)
Comprehensive loss	—	—	—	—	—	—	—	(20,204)
Balance, December 31, 2025	188,314	$ 1,883	70	$ 1,050	$1,951,185	$ 4	$ (1,939,789)	$ 14,333

See accompanying Notes to Consolidated Financial Statements.

HERON THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,		
	2025	2024	2023
Operating activities:			
Net loss	$ (20,195)	$ (13,580)	$ (110,559)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	10,339	12,962	32,854
Depreciation and amortization	2,314	2,492	2,899
Amortization of debt discount	744	751	133
Amortization of debt issuance costs	73	210	206
Accretion of discount on short-term investments	(739)	(2,143)	(1,739)
Retirement and impairment of property and equipment	414	4,409	617
(Gain)/Loss on disposal of property and equipment	—	(27)	10
Loss on extinguishment of debt	11,339	—	—
Change in operating assets and liabilities:			
Accounts receivable	(10,706)	(18,744)	(8,088)
Inventory	(31,052)	(11,050)	12,463
Prepaid expenses and other assets	878	(9,927)	15,426
Accounts payable	(2,715)	8,469	15
Accrued clinical and manufacturing liabilities	1,399	3,220	(2,177)
Accrued payroll and employee liabilities	(284)	330	(4,192)
Other accrued liabilities	10,600	99	3,343
Net cash used in operating activities	(27,591)	(22,529)	(58,789)
Investing activities:			
Purchases of short-term investments	(50,786)	(103,087)	(87,658)
Maturities and sales of short-term investments	67,014	123,480	107,185
Purchases of property and equipment	(317)	(1,706)	(1,545)
Proceeds from the sale of property and equipment	98	27	13
Net cash provided by investing activities	16,009	18,714	17,995
Financing activities:			
Net proceeds from the sale of common stock	18,307	—	29,755
Proceeds from sale of Series A Convertible Preferred Stock	7,862	—	—
Cash paid for convertible notes extinguishment	(125,000)	—	—
Cash paid for notes payable extinguishment	(25,000)	—	—
Net proceeds from convertible note issuance	31,864	—	—
Net proceeds from notes payable issuance	105,381	—	24,350
Proceeds from warrant exercises	—	—	1
Proceeds from purchases under the Employee Stock Purchase Plan	853	637	904
Receipts (payments) for stock issued under the equity incentive plan	160	303	(903)
Net cash provided by financing activities	14,427	940	54,107
Net increase (decrease) in cash and cash equivalents	2,845	(2,875)	13,313
Cash and cash equivalents at beginning of year	25,802	28,677	15,364
Cash and cash equivalents at end of year	$ 28,647	$ 25,802	$ 28,677
Supplemental disclosure of cash flow information:			
Interest paid	$ 6,512	$ 4,860	$ 3,059

See accompanying Notes to Consolidated Financial Statements.

HERON THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

We are a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard of care for acute care and oncology patients.

ZYNRELEF® (bupivacaine and meloxicam) extended-release solution ("ZYNRELEF") is approved in the United States ("U.S.") for the management of postoperative pain. APONVIE® (aprepitant) injectable emulsion ("APONVIE") is approved in the U.S. for the prevention of postoperative nausea and vomiting. CINVANTI® (aprepitant) injectable emulsion ("CINVANTI") and SUSTOL® (granisetron) extended-release injection ("SUSTOL") are both approved in the U.S. for the prevention of chemotherapy-induced nausea and vomiting.

As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $46.6 million. Based on our current operating plan and projections, management believes that the Company's cash, cash equivalents and short-term investments will be sufficient to meet the Company's anticipated cash requirements for a period of at least one year from the date this Annual Report on Form 10-K is filed with the U.S. Securities and Exchange Commission ("SEC").

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Heron Therapeutics, Inc. and its wholly-owned subsidiary, Heron Therapeutics B.V., which was organized in the Netherlands in March 2015. Heron Therapeutics B.V. has no operations and no material assets or liabilities, and there have been no significant transactions related to Heron Therapeutics B.V. since its inception.

Reclassification of Certain Expenses

The consolidated statements of operations and comprehensive loss for the year ended December 31, 2023 reflects reclassification of certain expenses from research and development to general and administrative expenses to align with the Company's presentation for the year ended December 31, 2024 and December 31, 2025, as a result of the restructuring implemented in 2023 and the realignment of the Company's departments. These reclassifications resulted in no change to total operating expenses, loss from operations or net loss and no pro forma financial information is necessary.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the U.S. ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Our significant accounting policies that involve significant judgment and estimates include revenue recognition, investments, inventory and the related reserves, accrued clinical and manufacturing liabilities, income taxes and stock-based compensation. Actual results could differ materially from those estimates.

Cash, Cash Equivalents and Short-term Investments

Cash and cash equivalents consist of cash and highly liquid investments with contractual maturities of three months or less from the original purchase date.

Short-term investments consist of securities with contractual maturities of greater than three months from the original purchase date. Securities with contractual maturities greater than one year are classified as short-term investments on the consolidated balance sheets, as we have the ability, if necessary, to liquidate these securities to meet our liquidity needs in the next 12 months. We have classified our short-term investments as available-for-sale securities in the accompanying consolidated financial statements. Available-for-sale securities are stated at fair

market value, with net changes in unrealized gains and losses reported in other comprehensive loss and realized gains and losses included in other (expense) income, net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income within other (expense) income, net.

Our bank and investment accounts have been placed under a control agreement in accordance with our Working Capital Facility Agreement (see Note 8).

Fair Value of Financial Instruments

A company may elect to use fair value to measure accounts receivable, available-for-sale securities, accounts payable, guarantees and issued debt, among others. If the use of fair value is elected, any upfront costs and fees related to the item such as debt issuance costs must be recognized in earnings and cannot be deferred. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. Unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings and any changes in fair value are recognized in earnings. We have elected to not apply the fair value option to our financial assets and liabilities.

Financial instruments, including cash and cash equivalents, receivables, inventory, prepaid expenses, other current assets, accounts payable and accrued expenses, are carried at cost, which is considered to be representative of their respective fair values because of the short-term maturity of these instruments. Short-term available-for-sale investments are carried at fair value. Our convertible notes and non-current notes payable outstanding at December 31, 2025 and 2024 do not have a readily available ascertainable market value, however, their carrying value, which is measured at carrying value less unamortized debt issuance costs or debt discounts, is considered to approximate their fair value as the terms were based on market conditions.

Concentration of Credit Risk

Cash, cash equivalents and short-term investments are financial instruments that potentially subject us to concentrations of credit risk. We deposit our cash in financial institutions. At times, such deposits may be in excess of insured limits. We have not experienced any losses in such accounts and believe we are not exposed to significant risk on our cash, cash equivalents and short-term investments. Any loss incurred or a lack of access to such funds could have a significant adverse impact on our financial condition, results of operations, and cash flows.

We may also invest our excess cash in money market funds, U.S. government and agencies, corporate debt securities and commercial paper. We have established guidelines relative to our diversification of our cash investments and their maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

ZYNRELEF, APONVIE, CINVANTI and SUSTOL (collectively, our "Products") are distributed in the U.S. through a limited number of specialty distributors and full line wholesalers (collectively, our "customers") that resell to healthcare providers and hospitals, the end users of our Products.

The following includes the percentage of net product sales and accounts receivable balances for our three major customers, each of which comprised 10% or more of our net product sales:

	Net Product Sales Year Ended December 31			Accounts Receivable As of December 31,	
	2025	2024	2023	2025	2024
Customer A	42.0%	43.3%	43.3%	42.0%	39.9%
Customer B	32.5%	36.1%	36.8%	29.4%	37.2%
Customer C	23.9%	19.4%	19.0%	28.1%	22.5%
Total	98.4%	98.8%	99.1%	99.5%	99.6%

Accounts Receivable, Net

Accounts receivable are recorded at the invoice amount, net of an allowance for credit losses. The allowance for credit losses reflects accounts receivable balances that are believed to be uncollectible. In estimating the

allowance for credit losses, we consider: (1) our historical experience with collections and write-offs; (2) the credit quality of our customers and any recent or anticipated changes thereto; (3) the outstanding balances and past due amounts from our customers; and (4) reasonable and supportable forecast of economic conditions expected to exist throughout the contractual term of the receivable.

As of December 31, 2025 and 2024, we determined that an allowance for credit losses was not required. For the years ended December 31, 2025, 2024 and 2023, we did not have any material write-offs of accounts receivable balances.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value on a FIFO basis. We periodically analyze our inventory levels and write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory quantities that are in excess of expected sales requirements as cost of product sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as cost of product sales.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets (generally five years). Leasehold improvements are stated at cost and amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term.

Impairment of Long-Lived Assets

If indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and record the impairment as a reduction in the carrying value of the related asset with a corresponding charge to operating expenses. Estimating the undiscounted future operating cash flows associated with long-lived assets requires judgment and assumptions that could differ materially from actual results.

Leases

We determine if an arrangement is a lease or contains lease components at inception. Operating leases with an initial term greater than 12 months are recorded as lease liabilities with corresponding right-of-use ("ROU") lease assets on the consolidated balance sheets. ROU lease assets represent our right to use the underlying assets over the lease term, and lease liabilities represent the present value of our obligation to make lease payments arising from the lease. Lease liabilities are recognized at the lease commencement based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. We use the implicit rate when readily determinable. The ROU lease assets equal the lease liabilities, less unamortized lease incentives, unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease. The lease term includes any option to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense is recognized on a straight-line basis over the lease term. We have elected the practical expedient to not separate lease and non-lease components.

Revenue Recognition

Revenue is recognized in accordance with the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("Topic 606"). Topic 606 is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

Product Sales

Our Products are distributed in the U.S. through a limited number of customers that resell to healthcare providers and hospitals, the end users of our Products.

Revenue is recognized in an amount that reflects the consideration we expect to receive in exchange for our Products. To determine revenue recognition for contracts with customers within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations of the contract(s); (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract(s); and (v) recognize revenue when (or as) we satisfy the performance obligations. We recognize revenue from product sales when there is a transfer of control of the product to our customers. We typically determine transfer of control based on when the product is delivered, and title passes to our customers.

Product Sales Allowances

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. Such variable consideration includes estimates that take into consideration the terms of our agreements with customers, historical product returns, rebates or discounts taken, the shelf life of the product and specific known market events, such as competitive pricing and new product introductions. If actual future results vary from our estimates, we may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. Our product sales allowances include:

- Product Returns - We allow the majority of our customers to return product for credit beginning three months prior to the product expiration date and up to 12 months after the product expiration date. As such, there may be a significant period of time between the time the product is shipped and the time the credit is issued on returned product.

- Distributor Fees - We pay distribution service fees to our customers based on a contractually fixed percentage of the wholesale acquisition cost and fees for data. These fees are paid no later than two months after the quarter in which product was shipped.

- Group Purchasing Organization ("GPO") Discounts and Rebates - We offer cash discounts to GPO members. These discounts are taken when the GPO members purchase product from our customers, who then charge back to us the discount amount. Additionally, we offer volume and contract-tier rebates to GPO members. Rebates are based on actual purchase levels during the quarterly rebate purchase period.

- GPO Administrative Fees - We pay administrative fees to GPOs for services and access to data. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the GPOs' members.

- Medicaid Rebates - We participate in Medicaid rebate programs, which provide assistance to certain low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, we pay a rebate to each participating state, generally within six months after the quarter in which the product was sold.

- Prompt Pay Discounts - We may provide discounts on product sales to our customers for prompt payment based on contractual terms.

We believe our estimated allowance for product returns and GPO discounts requires a high degree of judgment and is subject to change based on our experience and certain quantitative and qualitative factors. We believe our estimated allowances for distributor fees, GPO rebates and administrative fees, Medicaid rebates and prompt pay discounts do not require a high degree of judgment because the amounts are settled within a relatively short period of time.

Our product sales allowances and related accruals are evaluated each reporting period and adjusted when trends or significant events indicate that a change in estimate is appropriate. Changes in product sales allowance estimates could materially affect our results of operations and financial condition.

Accrued Clinical and Manufacturing Liabilities

We accrue clinical and manufacturing costs based on work performed, which relies on estimates of the progress of the work completed and the related expenses incurred. Manufacturing contracts vary significantly in duration, and may be for a fixed amount, based on the achievement of certain contingent events or deliverables, a variable amount based on actual costs incurred, capped at a certain limit or contain a combination of these elements. Revisions are recorded to research and development expense or inventory in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development expense or inventory. However, a modification could result in a material charge to our results of operations.

Research and Development Expense

All costs of research and development are expensed in the period incurred. Research and development expense primarily consists of personnel and related costs, stock-based compensation expense, fees paid to outside service providers and consultants, facilities costs and materials used in clinical and preclinical trials and research and development.

Patent Costs

We incur outside legal fees in connection with filing and maintaining our various patent applications. All patent costs are expensed as incurred and are included in general and administrative expense in the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation Expense

We estimate the fair value of each option grant using the Black-Scholes option pricing model and for market-based stock option grants using the Monte Carlo simulation model. This fair value is then amortized using the straight-line single-option method of attributing the value of stock-based compensation to expense over the requisite service periods of the awards. Forfeitures are accounted for, as incurred, as a reversal of stock-based compensation expense related to awards that will not vest. The Black-Scholes option pricing model and the Monte Carlo simulation model both require inputs of complex and subjective assumptions, including each option's expected life and price volatility of the underlying stock.

Warrants

We have issued warrants to purchase shares of our common stock in conjunction with certain equity and debt financings or in exchange for services. The terms of the warrants were evaluated to determine the appropriate classification as equity or a liability.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are calculated by applying existing tax laws and the rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the year of the enacted rate change.

We recognize the impact of a tax position in our consolidated financial statements if the position is more likely than not to be sustained on examination and on the technical merits of the position. The total amount of unrecognized tax benefits, if recognized, would affect other tax accounts, primarily deferred taxes in future periods, and would not affect our effective tax rate, since we maintain a full valuation allowance against our deferred tax assets (see Note 12). We recognize interest and penalties related to income tax matters in income tax expense.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net changes in unrealized gains and losses on available-for-sale securities are included in other comprehensive loss and represent the difference between our net loss and comprehensive loss for both periods presented.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, including pre-funded warrants to purchase shares of common stock. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options, restricted stock units, warrants and shares of common stock underlying convertible notes are considered to be common stock equivalents and are included in the calculation of diluted net loss per share only when their effect is dilutive.

Because we have incurred a net loss for all periods presented in the consolidated statements of operations and comprehensive loss, the following common stock equivalents were not included in the computation of net loss per share because their effect would be anti-dilutive (in thousands):

	December 31,		
	2025	2024	2023
Stock options outstanding	28,705	26,082	24,575
Restricted stock units outstanding	3,799	1,981	1,405
Warrants outstanding	298	298	298
Series A convertible preferred stock outstanding	700	—	—
Shares of common stock underlying convertible notes outstanding	19,444	9,819	9,819

Segment Reporting

Management, upon consideration of the organizational structure of the business and information reviewed by the Company's Chief Executive Officer, who is also the Company's chief operating decision maker ("CODM"), has concluded that we have one reportable segment. All revenues for the years ended December 31, 2025, 2024 and 2023 were generated from customers in the U.S. The CODM allocates resources and evaluates the performance of the reportable segment, which is the consolidated entity, primarily based on net loss as reported on the consolidated statements of operations and comprehensive loss. The significant expenses reviewed by the CODM are cost of product sales, research and development expenses, general and administrative expenses, and sales and marketing expenses as reported on the consolidated statements of operations and comprehensive loss. The Company's operating segments do not record intercompany revenue nor allocate any expenses. The CODM does not evaluate operating segments using discrete asset information.

Recent Accounting Pronouncements

Recently Adopted

In December 2023, FASB issued Accounting Standards Update No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), to enhance income tax reporting disclosures and require disclosure of specific categories in the tabular rate reconciliation. This standard is effective for fiscal years beginning after December 15, 2024. The guidance was adopted prospectively. See Note 12 - Income taxes for additional information.

In November 2024, the FASB issued ASU No. 2024-04, *Induced Conversions of Convertible Debt Instruments* ("ASU 2024-04"), to improve the consistency in application of the induced conversion guidance in Subtopic 470-20, Debt - Debt with Conversions and Other Options. We early adopted the provisions of ASU 2024-04 during the year ended December 31, 2025 and concluded that the settlement of the 2026 Convertible Notes did

not represent an induced conversion. Refer to Note 8 - Long-Term Debt and Convertible Notes for evaluation of the accounting of the transaction.

Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires disaggregated disclosures of certain categories of expenses that are included in the face of the financial statements. This standard is effective for fiscal years beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact on our disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements,* which provides clarity regarding the existing required interim GAAP disclosures. This standard is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact on our disclosures.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The FASB ASC Topic 820, *Fair Value Measurements & Disclosures*, establishes a fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

- Level 1—Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We measure cash, cash equivalents and short-term investments at fair value on a recurring basis. The fair values of such assets were as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Balance at December 31, 2025	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and money market funds	$ 22,313	$ 22,313	$ —	$ —
U.S. treasury bills and government agency obligations	9,534	9,534	—	—
U.S. corporate debt securities	7,035	—	7,035	—
Foreign corporate debt securities	2,225	—	2,225	—
Foreign commercial paper	3,979	—	3,979	—
U.S. commercial paper	1,545	—	1,545	—
Total	$ 46,631	$ 31,847	$ 14,784	$ —

	Fair Value Measurements at Reporting Date Using			
	Balance at December 31, 2024	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and money market funds	$ 23,860	$ 23,860	$ —	$ —
U.S. treasury bills and government agency obligations	14,868	14,868	—	—
U.S. corporate debt securities	13,644	—	13,644	—
Foreign corporate debt securities	5,913	—	5,913	—
Foreign commercial paper	998	—	998	—
Total	$ 59,283	$ 38,728	$ 20,555	$ —

We have not transferred any investment securities between the three levels of the fair value hierarchy.

As of December 31, 2025, cash equivalents included $11.6 million of available-for-sale securities with contractual maturities of three months or less and short-term investments included $5.4 million of available-for-sale securities with contractual maturities of three months to one year. As of December 31, 2024, cash equivalents included $1.9 million of available-for-sale securities with contractual maturities of three months or less and short-term investments included $9.0 million of available-for-sale securities with contractual maturities of three months to one year. The money market funds as of December 31, 2025 and 2024 are included in cash and cash equivalents on the consolidated balance sheets.

4. Balance Sheet Details

Short-Term Investments

The following is a summary of our short-term investments (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury bills and government agency obligations	$ 5,542	$ 2	$ —	$ 5,544
U.S. corporate debt securities	5,439	1	—	5,440
Foreign corporate debt securities	1,475	1	—	1,476
Foreign commercial paper	3,979	—	—	3,979
U.S. commercial paper	1,545	—	—	1,545
Total	$ 17,980	$ 4	$ —	$ 17,984

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury bills and government agency obligations	$ 14,860	$ 8	$ —	$ 14,868
U.S. corporate debt securities	11,699	3	—	11,702
Foreign corporate debt securities	5,911	2	—	5,913
Foreign commercial paper	998	—	—	998
Total	$ 33,468	$ 13	$ —	$ 33,481

The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. We regularly monitor and evaluate the realizable value of our marketable securities. We did not recognize any impairment losses for the years ended December 31, 2025, 2024 and 2023.

Unrealized gains and losses associated with our investments are reported in accumulated other comprehensive (loss) income. For the year ended December 31, 2025, we recorded $9,000 in net unrealized losses associated with our short-term investments. For the year ended December 31, 2024, we recorded no net unrealized gains or losses associated with our short-term investments. For the year ended December 31, 2023, we recorded $32,000 in net unrealized gains associated with our short-term investments.

Realized gains and losses associated with our investments, if any, are reported in the statements of operations and comprehensive loss. We did not recognize any realized gains or losses during the year ended December 31, 2025. We recognized $5,000 in realized gains during the year ended December 31, 2024, $1,000 in realized losses during the year ended December 31, 2023.

Inventory

Inventory consists of the following (in thousands):

	December 31,	
	2025	2024
Raw materials	$ 59,250	$ 19,733
Work in process	26,613	27,190
Finished goods	6,883	6,237
Total inventory	$ 92,746	$ 53,160

	December 31,	
	2025	2024
CINVANTI	$ 27,417	$ 36,484
SUSTOL	1,307	3,206
APONVIE	3,586	1,626
ZYNRELEF	60,436	11,844
Total inventory	$ 92,746	$ 53,160

The increase in raw materials during the year ended December 31, 2025 is for the purchase of polymer to support future production of ZYNRELEF.

Cost of product sales for the years ended December 31, 2025, 2024 and 2023 included charges of $4.6 million, $2.5 million and $20.3 million, respectively, relating to the reserves and write-offs of inventory.

Prepaid Expenses and Other Assets

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

	December 31,	
	2025	2024
Prepaid expenses	$ 11,796	$ 21,224
Prepaid insurance	1,956	2,203
Deposits	254	274
Interest receivables	160	263
Other receivables	344	209
Total prepaid expenses and other assets	$ 14,510	$ 24,173

Property and Equipment

Property and equipment, net consists of the following (in thousands):

	December 31,	
	2025	2024
Scientific equipment	$ 25,089	$ 30,342
Leasehold improvements	—	307
Computer equipment and software	18	1,047
Furniture, fixtures and office equipment	176	1,014
Property and equipment, gross	25,283	32,710
Less: accumulated depreciation and amortization	(12,880)	(17,847)
Property and equipment, net	$ 12,403	$ 14,863

Depreciation and amortization expense for the years ended December 31, 2025, 2024 and 2023 was $2.3 million, $2.5 million and $2.9 million, respectively. As of December 31, 2025 and 2024, $1.7 million and $2.6 million of property and equipment, respectively, was in process and not depreciated during the respective years.

Accrued Payroll and Employee Liabilities and Other Accrued Liabilities

Accrued payroll and employee liabilities consist of the following (in thousands):

	December 31,	
	2025	2024
Accrued employee salaries and benefits	$ 656	$ 1,591
Accrued bonuses	6,458	5,907
Accrued vacation	2,156	2,056
Total accrued payroll and employee liabilities	$ 9,270	$ 9,554

Other accrued liabilities consist of the following (in thousands):

	December 31,	
	2025	2024
Accrued product sales allowances	$ 45,995	$ 37,419
Accrued consulting and professional fees	2,707	3,036
Other accrued liabilities	1,631	1,063
Accrued interest	904	237
Total other accrued liabilities	$ 51,237	$ 41,755

5. Revenue Recognition

The following provides disaggregated net product sales (in thousands):

	For the Years Ended December 31,		
	2025	2024	2023
CINVANTI net product sales	$ 96,758	$ 100,079	$ 94,869
ZYNRELEF net product sales	38,072	25,546	17,727
APONVIE net product sales	11,571	4,518	1,391
SUSTOL net product sales	8,503	14,142	13,057
Total net product sales	$ 154,904	$ 144,285	$ 127,044

The following provides a summary of activity with respect to our product returns, distributor fees and discounts, rebates, administrative and other fees, which are included in other accrued liabilities on the consolidated balance sheets (in thousands):

	Product Returns	Distributor Fees	Discounts, Rebates, Administrative and Other Fees	Total
Balance at December 31, 2024	$ 3,791	$ 5,883	$ 27,745	$ 37,419
Provision	1,983	35,624	230,096	267,703
Payments/credits	(1,259)	(34,179)	(223,689)	(259,127)
Balance at December 31, 2025	$ 4,515	$ 7,328	$ 34,152	$ 45,995

6. Commitments and Contingencies

Litigation and other contingencies

The Company is, from time to time, subject to a variety of litigation and other proceedings incidental to its business, including lawsuits involving claims relating to intellectual property matters, employment matters, commercial disputes; as well as regulatory investigations or enforcement. The Company may also become subject to lawsuits as a result of past or future acquisitions, or as a result of liabilities retained from, or representations, warranties or indemnities provided in connection with divested businesses. Some of these lawsuits may include claims for

punitive and consequential as well as compensatory damages. Based upon experience, current information and applicable law, the Company does not believe that these proceedings and claims will have a material adverse effect on its financial position, results of operations or cash flows.

Leases

As of December 31, 2025, our operating lease for 52,148 square feet of laboratory and office space in San Diego, California expired. In October 2021, we entered into a sublease agreement to sublet 23,873 square feet of laboratory and office space in San Diego, California. The space was delivered to the subtenant in March 2022. As a result of the sublease agreement, our one five-year option to renew this lease on expiration applied only with respect to our remaining 28,275 square feet of laboratory and office space.

In September 2023, we entered into a sublease agreement to sublet 5,840 square feet of office space in Cary, North Carolina, with a lease term that expired on April 30, 2025.

In September 2024, we entered into a short-term sublease agreement to sublet 9,882 square feet of office space in Cary, North Carolina, with a lease term that expired on November 30, 2025.

In December 2025, we entered into a short-term lease agreement for 9,882 square feet of office space in Cary, North Carolina, with a lease term that expires on February 28, 2026.

In August 2025, we entered into a lease agreement for 16,837 square feet of office space in Cary, North Carolina, with the lease term expected to commence no later than May 25, 2026 ("lease commencement date") and expire 111 months from the lease commencement date, with the option to extend for one additional period of 84 months upon written notice. As the lease commencement date has not yet occurred, no right-of-use asset or lease liability has been recognized in the accompanying condensed consolidated financial statements. We provided the landlord with a letter of credit for $0.2 million, which is included within cash and cash equivalents in the condensed consolidated balance sheet.

Rent expense under all operating leases totaled $3.1 million, $3.0 million and $2.9 million for the years ended December 31, 2025, 2024 and 2023, respectively. During the years ended December 31, 2025, 2024 and 2023, we paid $3.2 million, $3.2 million and $3.0 million, respectively, for our operating leases.

Sublease rental income for the San Diego, CA sublease totaled $1.3 million, $1.3 million and $1.2 million for the years ended December 31, 2025, 2024 and 2023.

Development Agreements

We enter into agreements with contract manufacturing organizations for the manufacture and supply of commercial materials and drug product. In some of our agreements with contract manufacturing organizations, we are required to meet minimum purchase obligations. Under certain of these agreements, we may be subject to penalties in the event that we prematurely terminate these agreements. At this time, due to the variability associated with contract manufacturing agreements, we are unable to estimate with certainty the future costs we will incur. We intend to use our current financial resources to fund our obligations under these commitments.

Purchase Obligations

On December 31, 2025, purchase obligations primarily consisted of non-cancellable commitments with third-party manufacturers in connection with the manufacturing of our commercial products. Total purchase obligations of $19.0 million were not included in our consolidated financial statements for the year ended December 31, 2025, all of which are due within one year.

7. Reorganization

June 2023 Reorganization

In June 2023, we implemented a restructuring plan under which we provided certain employees with one-time severance payments upon termination, continuation of benefits for a specific period of time, outplacement services and certain stock award modifications. During the year ended December 31, 2023, we recognized $4.2 million of expense, $2.4 million of which was included in sales and marketing expense, $1.7 million of which was included in

research and development expense and $0.1 million of which was included in general and administrative expense. As of December 31, 2024, we paid all of the total cash severance charges.

Executive Officer Departures

During the second and third quarters of 2023, we implemented changes to our executive leadership structure. In connection with these changes, we provided five executive officers with one-time severance payments upon termination, continued benefits for a specified period of time, and certain stock award modifications. The total expense for these activities was $13.4 million, $4.7 million of which was primarily for severance and $8.7 million of which was for non-cash, stock-based compensation expense. During the year ended December 31, 2023, we recognized the $13.4 million of expense, $7.2 million of which was included in general and administrative expense, $3.9 million of which was included in sales and marketing expense, and $2.3 million of which was included in research and development expense. As of December 31, 2024, we paid all of the total cash severance charges.

We have accounted for these expenses in accordance with the FASB ASC Topic 420, *Exit or Disposal Cost Obligations*.

8. Long-Term Debt and Convertible Notes

Working Capital Facility Agreement

On August 9, 2023, we entered into a working capital facility agreement (the "Initial Working Capital Facility Agreement") with Hercules Capital, Inc., as administrative agent, collateral agent, and lender (the "Lender"). The Initial Working Capital Facility Agreement provided for an aggregate principal amount of up to $50.0 million with tranched availability as follows: (i) $25.0 million at closing on August 9, 2023 ("tranche 1A"), (ii) $5.0 million available through December 15, 2024 ("tranche 1B") and (iii) $20.0 million available from the earlier of: (a) the full draw of tranche 1B and (b) the expiration of tranche 1B, and available through December 15, 2025 ("tranche 1C"), and in the case of tranches 1B and 1C, subject to certain customary conditions to draw down.

The Initial Working Capital Facility Agreement had a term of four years, with a springing maturity date that was 91 days prior to the stated maturity of our 2026 Convertible Notes (as defined below), if still outstanding at such time. The loans thereunder did not have any scheduled amortization payments and accrued interest at a floating rate equal to 9.95% per annum, payable in cash on a monthly basis and upon maturity or payoff. In addition, any loans under the Initial Working Capital Facility Agreement also accrued paid-in-kind interest at a fixed rate of 1.5% per annum which was due upon maturity or payoff.

In addition, in connection with the tranche 1A funding, we issued warrants to the Lender to purchase up to 297,619 shares of our common stock at an exercise price of $1.68 per share (the "Lender Warrants"). The Lender Warrants are equal to 2.00% of the principal amount of the tranche 1A loans funded by the Lender (the "Warrant Coverage"). The Initial Working Capital Facility Agreement also required that we issue additional warrants to the Lender at the time of each draw down of tranches 1B and 1C with the same Warrant Coverage. Each Lender Warrant is exercisable for seven years from the date of issuance. The Lender Warrant issued in conjunction with the tranche 1A funding remains outstanding on December 31, 2025.

On February 13, 2025, we entered into an amendment to the Initial Working Capital Facility Agreement (the "First Amendment to the Working Capital Facility Agreement") to extend the maturity date to the earlier of (a) September 1, 2027 and (b) to the extent that any of the 2026 Convertible Notes remain outstanding on such date, (i) May 12, 2026 or (ii) in the event that the maturity date of any 2026 Convertible Notes is extended, prior to May 12, 2026, to August 11, 2026, or later, the date that is 91 days prior to the maturity date of such further extended 2026 Convertible Notes.

On August 8, 2025, we entered into an amendment to the Initial Working Capital Facility Agreement, as amended by the First Amendment to the Working Capital Facility Agreement (the "Second Amendment to the Working Capital Facility Agreement"). The Second Amendment to the Working Capital Facility Agreement (i) provides for an aggregate principal amount of up to $150.0 million plus the accrued and unpaid paid-in-kind interest on the existing debt under the Initial Working Capital Facility Agreement at closing on August 12, 2025, (ii) extends the maturity date under the First Amendment to the Working Capital Facility Agreement to September 1, 2030, (iii) adjusts the interest rate to Prime, with a 7.5% floor, plus 1.95%, (iv) adjusts the paid-in-kind interest rate to 1.0% per annum, which is due upon maturity or payoff, (iv) provides for payment of a 1.0% upfront facility charge and an

end of term charge of up to 6.25% of principal drawn. The loans under the Second Amendment to the Working Capital Facility Agreement do not have any scheduled amortization payments. The approximately $150.0 million aggregate principal has tranched availability as follows: (i) $110.0 million plus capitalized paid-in-kind interest of approximately $0.8 million on August 12, 2025 ("tranche 1"), (ii) $20.0 million available through December 15, 2026 ("tranche 2") and (iii) $20.0 million available from the earlier of: (a) the full draw of tranche 2 and (b) September 30, 2027 ("tranche 3"), and in the case of tranches 2 and 3, subject to certain customary conditions to draw down.

The Second Amendment to the Working Capital Facility Agreement contains a minimum cash covenant, a minimum revenue covenant and a minimum EBITDA covenant. The Second Amendment to the Working Capital Facility Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. We were in compliance with all covenants of the Second Amendment to the Working Capital Facility Agreement as of December 31, 2025.

On January 30, 2026, we entered into an amendment to the Initial Working Capital Facility Agreement, as amended by the First Amendment to the Working Capital Facility Agreement and the Second Amendment to the Working Capital Facility Agreement (the “Third Amendment to Working Capital Facility Agreement”) to increase the end of term charge to be up to 6.50%, depending on the end of term.

The Initial Working Capital Facility Agreement, together with the First Amendment to the Working Capital Facility Agreement, the Second Amendment to the Working Capital Facility Agreement and the Third Amendment to the Working Capital Facility Agreement are referred to collectively as the "Working Capital Facility Agreement".

The Second Amendment to the Working Capital Facility Agreement was accounted for in accordance with ASC Topic 470, *Debt*. Amendments are assessed by management to determine appropriate treatment as troubled debt restructurings, extinguishments or modifications. The Second Amendment to the Working Capital Facility Agreement qualifies as a debt extinguishment and issuance of a new debt instrument. We recorded a loss on extinguishment during the year ended December 31, 2025, of $5.5 million, equal to the carrying value of the Second Amendment to the Working Capital Facility Agreement less the carrying value of the First Working Capital Facility Agreement on August 12, 2025 of $0.3 million, the facility charge of $1.1 million paid to the lenders, the remaining Initial Working Capital Facility Agreement end of term fee of $0.2 million and the present value of Second Amendment to the Working Capital Facility Agreement end of term fee of $3.9 million. The Initial Working Capital Facility Agreement end of term fee is payable on September 1, 2027. The remaining Second Amendment to the Working Capital Facility Agreement end of term fee will be accreted to interest expense over the term of the agreement using the effective interest rate method.

The tranche 1 funding under the Second Amendment to the Working Capital Facility Agreement of $110.0 million plus the accrued and unpaid paid-in-kind interest of $0.7 million from the Initial Working Capital Facility Agreement are accounted for as debt and was recorded as a liability on the condensed consolidated balance sheets. In addition, the additional borrowings available under the Second Amendment to the Working Capital Facility Agreement are accounted for as a single freestanding financial instrument that are not assets or obligations of ours and will be accounted for when and if we borrow additional tranches in the future.

In connection with the Second Amendment to the Working Capital Facility Agreement, we incurred debt issuance costs of $3.5 million, which was recorded as a debt discount. The debt discount is being amortized into interest expense using the effective interest rate method over the term of the Second Amendment to the Working Capital Facility Agreement. The effective interest rate as of December 31, 2025 is 11.6%.

For the year ended December 31, 2025, interest expense related to the Working Capital Facility Agreement was $7.1 million, which included $5.7 million related to the stated interest rate, $0.7 million related to paid-in-kind interest, and $0.7 million related to the amortization of the debt discounts and accretion of the end of term fee.

For the year ended December 31, 2024, interest expense related to the Working Capital Facility Agreement was $3.7 million, which included $2.6 million related to the stated interest rate, $0.4 million related to paid-in-kind interest, and $0.7 million related to the amortization of the debt discounts and accretion of the end of term fee.

For the year ended December 31, 2023, interest expense related to the Working Capital Facility Agreement was $1.3 million, which included $1.0 million related to the stated interest rate, $0.2 million related to paid-in-kind interest and $0.1 million related to the amortization of the debt discounts and accretion of the end of term fee.

As of December 31, 2025, the carrying value of the Working Capital Facility Agreement was $107.9 million, which is comprised of the $110.8 million principal amount outstanding, $0.4 million of accumulated paid-in-kind interest, less debt discounts of $3.3 million. The end of term fee accreted as of December 31, 2025, of $4.8 million is recorded in other non-current liabilities on the condensed consolidated balance sheets.

As of December 31, 2024, the carrying value of the Working Capital Facility Agreement was $25.0 million, which is comprised of the $25.0 million principal amount outstanding, and $0.5 million of accumulated paid-in-kind interest, less debt discounts of $0.5 million. The end of term fee accreted as of December 31, 2024, of $0.4 million is recorded in other non-current liabilities on the condensed consolidated balance sheets.

2026 Senior Unsecured Convertible Notes

In May 2021, we entered into a note purchase agreement with funds affiliated with Baker Bros. Advisors LP for a private placement of $150.0 million aggregate principal amount of senior unsecured convertible notes due in 2026 (the "2026 Convertible Notes"). We received a total of $149.0 million, net of issuance costs, from the issuance of the 2026 Convertible Notes.

The 2026 Convertible Notes bear interest at a rate of 1.5% per annum, payable in cash semi-annually in arrears on June 15 and December 15 of each year with a maturity date of May 26, 2026, unless earlier converted, redeemed or repurchased.

The 2026 Convertible Notes were accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options ("ASC 470-20"), and ASC Subtopic 815-40, Contracts in Entity's Own Equity ("ASC 815-40"). Under ASC 815-40, to qualify for equity classification (or non-bifurcation, if embedded), the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. Based upon our analysis, it was determined that the 2026 Convertible Notes do contain embedded features indexed to our common stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and, also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the 2026 Convertible Notes were recorded as a liability on the condensed consolidated balance sheets.

We incurred issuance costs related to the 2026 Convertible Notes of $1.0 million, which we recorded as debt issuance costs and were included as a reduction to the 2026 Convertible Notes on the condensed consolidated balance sheets. The debt issuance costs are being amortized to interest expense using the effective interest rate method over the term of the 2026 Convertible Notes, resulting in an effective interest rate of 1.6%.

On August 8, 2025, we entered into an exchange agreement pursuant to which $150.0 million aggregate principal amount of the 2026 Convertible Notes outstanding were exchanged for (i) 16,666,666 shares of common stock for an aggregate principal amount of $25.0 million of the 2026 Convertible Notes and (ii) the remaining $125.0 million plus accrued and unpaid interest under the 2026 Convertible Notes paid in cash, and which closed on August 12, 2025. As of December 31, 2025, no 2026 Convertible Notes remain outstanding.

The exchange agreement was accounted for in accordance with ASC 470-20, after the adoption of ASU 2024-04, whereby we concluded that the exchange did not qualify as an induced conversion. Thus, we accounted for the exchange as a debt extinguishment. We recorded a loss on extinguishment during the year ended December 31, 2025 of $5.8 million, which was equal to the carrying value of the 2026 Convertible Notes less the fair value of the consideration offered in the exchange. The fair value of the consideration offered in the exchange was determined to be $125.0 million for the cash consideration and $30.7 million for the common shares offered. The fair value of the common stock exchanged was determined using the closing price of the common stock on August 7, 2025.

For the year ended December 31, 2025, interest expense related to the 2026 Convertible Notes was $1.6 million, which included $1.5 million related to the stated interest rate and $0.1 million related to the amortization of debt issuance costs.

For the year ended December 31, 2024, interest expense related to the 2026 Senior Convertible Notes was $2.4 million, which included $2.2 million related to the stated interest rate and $0.2 million related to the amortization of debt issuance costs.

For the year ended December 31, 2023, interest expense related to the 2026Senior Convertible Notes was $2.5 million, which included $2.3 million related to the stated interest rate and $0.2 million related to the amortization of debt issuance costs.

2031 Senior Unsecured Convertible Notes

On August 8, 2025, we entered into a note purchase agreement with a fund affiliated with Rubric Capital Management LP, for a private placement of $35.0 million aggregate principal amount of senior unsecured convertible notes due 2031 (the "2031 Convertible Notes"), which closed on August 12, 2025. We received a total of $31.9 million, net of issuance costs and original issuance discount, from the issuance of the 2031 Convertible Notes.

The 2031 Convertible Notes were issued at par. The 2031 Convertible Notes bear interest at a rate of 5.0% per annum, payable in cash semi-annually in arrears on March 1 and September 1 of each year, or at a rate of 7.0% per annum for paid-in-kind interest prior to September 1, 2026. The 2031 Convertible Notes mature on March 1, 2031, unless earlier converted, redeemed or repurchased.

The 2031 Convertible Notes are subject to redemption at our option, after September 1, 2026, but only if the last reported sale price per share of our common stock exceeds 200% of the conversion price for a specified period of time. The redemption price will be equal to the principal amount of the 2031 Convertible Notes to be redeemed, plus accrued and unpaid interest.

The 2031 Convertible Notes can be settled in either shares of common stock, cash or a combination of cash and shares of common stock based on the conversion rate in effect on the date of conversion. The initial conversion rate for the 2031 Convertible Notes is 555.5556 shares per $1,000 principal amount of the 2031 Convertible Notes (equivalent to an initial conversion price of $1.80 per share of common stock), subject to certain adjustments.

If a holder of the 2031 Convertible Notes converts upon a make-whole fundamental change or Company redemption, the holder may be eligible to receive a make-whole premium through an increase to the conversion rate.

The 19,444,444 shares of common stock issuable upon the conversion, at the option of the holder, of the 2031 Convertible Notes, which includes the maximum number of shares of common stock issuable under the make-whole premium, are registered for resale pursuant to a registration statement filed with and declared effective by the SEC in September 2025.

At a special meeting of stockholders held on October 13, 2025, the Company’s stockholders approved, pursuant to Nasdaq Listing Rule 5635(d), the issuance of shares of common stock in connection with the conversion of the 2031 Convertible Notes, which could, under certain circumstances that may occur in the future, exceed 19.99% of the number of shares of the common stock issued and outstanding prior to such issuance.

The 2031 Convertible Notes were accounted for in accordance with ASC 470-20 and ASC 815-40. Under ASC 815-40, to qualify for equity classification (or non-bifurcation, if embedded), the instrument (or embedded feature) must be both (1) indexed to the issuer's stock and (2) meet the requirements of the equity classification guidance. Based upon our analysis, it was determined that the 2031 Convertible Notes do contain embedded features indexed to our common stock, but do not meet the requirements for bifurcation, and therefore do not need to be separately accounted for as an equity component. Since the embedded conversion feature meets the equity scope exception from derivative accounting, and, also since the embedded conversion option does not need to be separately accounted for as an equity component under ASC 470-20, the proceeds received from the issuance of the 2031 Convertible Notes were recorded as a liability on the condensed consolidated balance sheets.

We incurred issuance costs related to the 2031 Convertible Notes of $1.4 million, which we recorded as debt issuance costs and are included as a reduction to the 2031 Convertible Notes on the condensed consolidated balance sheets. We also incurred an original issuance discount of $1.8 million, which we recorded as a reduction to the 2031 Convertible Notes on the condensed consolidated balance sheets. The debt issuance costs and original issuance discount are being amortized to interest expense using the effective interest rate method over the term of the 2031 Convertible Notes, resulting in an effective interest rate of 7.14%.

For the year ended December 31, 2025, interest expense related to the 2031 Convertible Notes was $0.9 million, which included $0.9 million related to paid-in-kind interest and nil related to the amortization of debt issuance costs.

As of December 31, 2025, the carrying value of the 2031 Convertible Notes was $32.7 million, which is comprised of the $35.0 million principal amount of the 2031 Convertible Notes outstanding, $0.9 million of accumulated paid-in-kind interest, less debt issuance costs of $3.2 million.

9. Stockholders' Equity

2025 Private Placement

On August 8, 2025, we entered into a securities purchase agreement with the purchasers party thereto, for a private placement of (i) 13,225,227 shares of common stock at a purchase price of $1.50 per share and (ii) 524,141 shares of Series A convertible preferred stock, which would automatically convert upon stockholder approval and subject to beneficial ownership limitations, into 5,241,410 shares of common stock, at a conversion price of $1.50 per share (stated value of $15.00 per share) for aggregate gross proceeds of $27.7 million, and which closed on August 12, 2025. In connection with the private placement equity offering, we incurred issuance costs of $1.5 million. The Series A convertible preferred stock is convertible to common stock at a ratio of ten shares of common stock for each share of Series A convertible preferred stock and has a par value of $0.01. The Series A convertible preferred stock ranks senior to common stock with respect to dividend rights and rights on the distribution of assets in an event of liquidation. The Series A convertible preferred stockholders have no voting rights and are entitled to receive dividends on an as converted basis in the same form as dividends granted to holders of common stock. Upon a liquidation, the proceeds available for distribution would be paid pari passu among the holders of shares of common stock and Series A convertible preferred stock, pro rata based on the number of shares held by each such holder and on an as converted basis.

We evaluated the terms of the Series A convertible preferred stock under the guidance of ASC 480-10, Distinguishing Liabilities from Equity, and ASC 815-40 and recorded the Series A convertible preferred stock in stockholders' equity in the condensed consolidated balance sheets.

The 13,225,227 shares of common stock and 5,241,410 shares of common stock issuable upon automatic conversion of the Series A convertible preferred stock are registered for resale pursuant to a registration statement filed with and declared effective by the SEC in September 2025.

At a special meeting of stockholders held on October 13, 2025, the Company's stockholders approved, pursuant to Nasdaq Listing Rule 5635(d), the issuance of shares of common stock in connection with the conversion of the Series A convertible preferred stock, which could, under certain circumstances that may occur in the future, exceed 19.99% of the number of shares of the common stock issued and outstanding prior to such issuance.

Upon shareholder approval in October 2025, 454,129 shares of Series A convertible preferred stock were converted to common stock, resulting in the issuance of 4,541,290 shares of common stock. The remaining 70,012 shares of Series A convertible preferred stock are subject to beneficial ownership limitations and thus did not convert to common stock as of December 31, 2025.

2023 Private Placement

On July 21, 2023, we entered into a Securities Purchase Agreement (the "2023 Private Placement") with the purchasers party thereto, whereby we sold 20.7 million shares of our common stock in a private placement at a purchase price of $1.37 per share. In addition, as a component of the 2023 Private Placement, we sold 1.2 million pre-funded warrants to purchase shares of our common stock at a purchase price of $1.3699 per share. The pre-funded warrants have an exercise price of $0.0001 per share. The total net proceeds from the sale of the common stock and pre-funded warrants was $29.8 million (net of $0.2 million in issuance costs). The 2023 Private Placement closed on July 25, 2023. The aggregate 21.9 million shares of our common stock issued pursuant to the 2023 Private Placement are registered for resale pursuant to a registration statement filed with and declared effective by the SEC in August 2023.

Common Stock Reserved for Future Issuance

Shares of our common stock reserved for future issuance as of December 31, 2025 were as follows (in thousands):

	Number of Shares
Stock options outstanding	28,705
Restricted stock units outstanding	3,799
Shares available for future grants under the Amended & Restated 2007 Equity Incentive Plan	8,493
Shares of common stock reserved under the Employee Stock Purchase Plan	230
Shares of common stock underlying warrants	298
Shares of common stock underlying Series A Convertible Preferred Stock (see Note 9)	700
Shares of common stock underlying convertible notes outstanding (see Note 8)	19,444
Total shares reserved for future issuance	61,669

10. Equity Incentive Plans

Employee Stock Purchase Plan

In 1997, our stockholders approved our Employee Stock Purchase Plan ("ESPP"). As of December 31, 2025, a total of 3,425,000 shares are reserved for our ESPP. Under the terms of the ESPP, employees can elect to have up to a maximum of 10% of their base earnings withheld to purchase shares of our common stock. The purchase price of the stock is 85% of the lower of the closing prices for our common stock on either: (i) the first trading day in the enrollment period, as defined in the ESPP, in which the purchase is made, or (ii) the purchase date. The length of the enrollment period is 6 months. Enrollment dates are the first business day of May and November. Under the ESPP, we issued 658,274 and 639,681 shares in 2025 and 2024, respectively.

The weighted-average exercise price per share of the purchase rights exercised during 2025 and 2024 was $1.30 and $1.00, respectively. As of December 31, 2025, 3,195,400 shares of common stock have been issued under the ESPP and 229,600 shares of common stock are available for future issuance.

Equity Incentive Plan

We currently have one equity incentive plan from which we can grant options, restricted stock awards, restricted stock units ("RSUs"), and stock appreciation rights to employees, officers, directors and consultants. The stockholders approved our 2007 Amended and Restated Equity Incentive Plan ("2007 Plan") and as of December 31, 2025, 46,690,000 shares of common stock are authorized for issuance under the 2007 Plan. On December 31, 2025, there were 8,493,275 shares available for future grant under the 2007 Plan. Any shares that are subject to awards granted pursuant to the 2007 Plan that expire, are cancelled or are forfeited are available for future grant under the 2007 Plan.

In 2025, we granted options and RSUs to certain employees outside of the 2007 Plan as inducement equity awards. All such options to purchase our common stock were granted with an exercise price that equals fair market value of the underlying common stock on the grant dates and expire no later than 10 years from the date of grant. The options are exercisable in accordance with vesting schedules that generally provide for them to be fully vested and exercisable four years after the date of grant. All such RSUs vest ratably over four years. All stock options and RSU granted as inducement equity awards were approved by our Board of Directors and have been registered on Form S-8 with the SEC.

The following table summarizes the stock option activity for the year ended December 31, 2025:

	Outstanding Options	
	Number of Shares	Weighted-Average Exercise Price
Balance at December 31, 2024	26,082	$ 4.46
Granted	6,511	$ 1.81
Exercised	(287)	$ 1.46
Cancelled	(3,601)	$ 11.73
Balance at December 31, 2025	28,705	$ 2.98

The following table summarizes the RSU activity for the year ended December 31, 2025:

	Outstanding RSUs	
	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2024	1,981	$ 2.35
Granted	2,956	$ 1.81
Released	(881)	$ 2.40
Forfeited	(257)	$ 2.43
Balance at December 31, 2025	3,799	$ 1.91

As of December 31, 2025, options outstanding have a weighted-average remaining contractual term of 7.64 years and options exercisable have a weighted-average remaining contractual term of 6.98 years.

Total intrinsic value of options outstanding, which is the excess of the closing price of our common stock on the last trading day of the calendar year and the exercise price, was $0.5 million on December 31, 2025, $1.5 million on December 31, 2024 and $2.8 million on December 31, 2023.

The total intrinsic value of stock option exercises, which is the difference between the exercise price and closing price of our common stock on the date of exercise, during the years ended December 31, 2025, 2024 and 2023 was $167,000, $385,000 and $10,000, respectively.

As of December 31, 2025, 2024 and 2023, the total intrinsic value of options outstanding and exercisable was $0.2 million, $0.4 million and $0.1 million, respectively.

	Years Ended December 31,					
	2025		2024		2023	
	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price
Exercisable at end of year	11,807	$ 4.64	9,589	$ 8.88	11,390	$ 12.87
Options vested or expected to vest	28,705	$ 2.98	26,082	$ 4.46	24,575	$ 7.06

Exercise prices and weighted-average remaining contractual lives for the options outstanding as of December 31, 2025 were:

Outstanding Options	Range of Exercise Prices	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Remaining Contractual Life (in years) of Options Exercisable	Weighted-Average Exercise Price of Options Exercisable
5,033	$0.97 - $1.51	7.64	$ 1.22	2,055	7.34	$ 1.26
17,215	$1.52 - $2.28	8.00	1.84	5,796	7.95	1.89
4,543	$2.32 - $3.48	8.00	2.67	2,070	7.05	2.87
56	$3.66 - $5.49	7.56	3.81	30	7.01	3.88
20	$5.50 - $8.25	6.24	5.87	18	6.24	5.86
321	$9.05 - $14.49	4.40	12.26	321	4.40	12.26
874	$14.87 - $22.305	3.14	16.44	874	3.14	16.44
583	$23.15 - $34.725	3.33	24.90	583	3.33	24.90
60	$38.20 - $57.30	2.65	38.38	60	2.65	38.38
28,705		7.64	$ 2.98	11,807	6.98	$ 4.64

Included within outstanding options of 28,705 at December 31, 2025 was 6,350 market-based stock option awards.

On December 31, 2025, we had reserved 32,503,914 shares of common stock for future issuance upon exercise of outstanding options and vesting of outstanding restricted stock units granted under the 2007 Plan, as well as the inducement award grants.

Stock-Based Compensation

The following summarizes stock-based compensation expense related to stock-based payment awards pursuant to our equity compensation arrangements (in thousands):

	December 31,		
	2025	2024	2023
Research and development	$ 1,033	$ 1,856	$ 6,505
General and administrative	7,200	7,138	16,846
Sales and marketing	2,106	3,968	9,503
Total stock-based compensation expense	$ 10,339	$ 12,962	$ 32,854

As of December 31, 2025, there was $22.0 million of total unrecognized compensation cost related to non-vested, stock-based payment awards granted under all of our equity compensation plans and all non-plan option grants. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. We expect to recognize this compensation cost over a weighted-average period of 2.2 years.

The fair value of RSUs is estimated based on the closing market price of our common stock on the date of the grant. RSUs generally vest quarterly over a four-year period.

We estimated the fair value of each option grant and ESPP purchase right on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

Options:

	December 31,		
	2025	2024	2023
Risk-free interest rate	4.0%	4.5%	3.7%
Dividend yield	—%	—%	—%
Volatility	79.9%	80.1%	68.1%
Expected life (years)	6	6	6 to 10

ESPP:

	December 31,		
	2025	2024	2023
Risk-free interest rate	4.1%	4.9%	5.3%
Dividend yield	—%	—%	—%
Volatility	72.5%	95.3%	99.6%
Expected life (months)	6	6	6

The weighted-average grant date fair value of options granted was $1.32, $1.40 and $1.13 for the years ended December 31, 2025, 2024, and 2023 respectively.

The weighted-average fair value of shares purchased through the ESPP was $1.68, $1.53 and $0.64 for the years ended December 31, 2025, 2024 and 2023, respectively.

The risk-free interest rate assumption is based on observed interest rates on U.S. Treasury debt securities with maturities close to the expected term of our employee and director stock options and ESPP purchases.

The dividend yield assumption is based on our history and expectation of dividend payouts. We have never paid dividends on our common stock, and we do not anticipate paying dividends in the foreseeable future.

We used our historical stock price to estimate volatility.

The expected life of employee and director stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. We have elected to use the simplified method, as we do not have enough historical exercise experience to provide a reasonable basis on which to estimate the expected term. The expected life for the ESPP purchase rights is six months, which represents the length of each purchase period.

11. Employee Benefit Plan

We have a defined contribution 401(k) plan ("Plan") covering substantially all of our employees. For the year ended December 31, 2025 and 2024, we made matching cash contributions equal to 50% of each participant's contribution during the Plan year up to 6% per pay period. For the year ended December 31, 2023, we made matching cash contributions equal to 50% of each participant’s contribution during the Plan year up to a maximum amount equal to the lesser of 3% of each participant’s annual compensation or $9,900. Such amounts were recorded as expense in the corresponding years. We may also contribute additional discretionary amounts to the Plan as we determine. For the years ended December 31, 2025, 2024 and 2023, we contributed $0.8 million, $0.7 million, and $1.0 million, respectively, to the Plan. No discretionary contributions have been made to the Plan since its inception.

12. Income Taxes

For the years ended December 31, 2024, 2023 and 2022, we did not record a provision for income taxes due to a full valuation allowance against our deferred tax assets.

Following the adoption of ASU 2023-09, our tax provision and effective tax rate differed from the statutory federal rate as follows:

	December 31, 2025	
	Amount	Percent
Provision for income taxes at statutory federal income tax rate	$ (4,241)	21.0%
State income taxes, net of federal income tax effect	—	—
Non-taxable or non-deductible items:		
Stock-based compensation expense	5,701	(28.3%)
Non-deductible compensation	(2,595)	12.9%
Loss on debt extinguishment	2,381	(11.8%)
Change in valuation allowance	(1,633)	8.1%
Other reconciling items:		
Provision to return adjustment	241	(1.2%)
Other	146	(0.7%)
Total tax provision and effective tax rate	$ —	—

State taxes paid for all states where we are required to file was less than $10,000 during the year ended December 31, 2025. Alabama, California, and Tennessee made up the majority (greater than 50%) of the tax effect in the state tax, net of federal benefit category.

Prior to the adoption of ASU 2023-09, our tax provision and effective tax rate differed from the statutory federal rate as follows:

	2024		2023	
	Amount	Percent	Amount	Percent
Provision for income taxes at statutory federal income tax rate	$ (2,852)	21.0%	$ (23,210)	21.0%
State income taxes, net of federal income tax effect	1,513	(11.1%)	(1,460)	1.3%
Stock-based compensation expense	7,968	(58.7%)	19,022	(17.2%)
Non-deductible compensation	2,630	(19.4%)	(4,682)	4.2%
Change in valuation allowance	(10,392)	76.5%	7,556	(6.8%)
Provision to return adjustment	285	(2.1%)	3,008	(2.7%)
Other	848	(6.2%)	(234)	0.2%
Total tax provision and effective tax rate	$ —	—	$ —	—

Deferred income tax assets and liabilities arising from differences between accounting for financial statement purposes and tax purposes, less valuation allowance at year-end are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforward	$ 329,398	$ 324,175
Research and development credits	57,020	59,168
Section 174 capitalized research and development	17,954	25,117
Stock-based compensation	3,985	5,323
Lease liabilities	—	762
Other	6,642	5,262
Total gross deferred tax assets	414,999	419,807
Deferred tax liabilities:		
Right-of-use lease assets	—	(699)
Total gross deferred tax liabilities	—	(699)
Valuation allowance	(414,999)	(419,108)
Net deferred tax assets	$ —	$ —

We have established a valuation allowance to offset net deferred tax assets as of December 31, 2025 and 2024 due to the uncertainty of realizing future tax benefits from such assets.

As of December 31, 2025, we had federal net operating loss ("NOL") carryforwards of $1.3 billion and state NOL carryforwards of $0.9 billion. The federal NOL carryforwards consist of $541.7 million generated before January 1, 2018, which began to expire in 2025, and $793.9 million that can be carried forward indefinitely, but are subject to the 80% taxable income limitation. The state NOL carryforwards will begin to expire in 2028.

As of December 31, 2025 and December 31, 2024, we had federal and state research and development credit carryforwards of $44.1 million and $44.4 million, respectively. The federal research and development credit carryforwards began to expire in 2025. The state research and development credit carryforwards will be carried forward indefinitely.

Internal Revenue Code ("IRC") Sections 382 and 383 place a limitation on the amount of taxable income that can be offset by NOL and credit carryforwards after a change in control (generally greater than 50% change in ownership within a three-year period) of a loss corporation. Generally, after a change in control, a loss corporation cannot deduct NOL and credit carryforwards in excess of the IRC Sections 382 and 383 limitation. State jurisdictions have similar rules. We have performed an analysis of IRC Sections 382 and 383 through August 2025 and determined there were ownership changes in 2007, 2011 and 2013. The limitation in the federal and state NOL and research and development credit carryforwards that expire unused would reduce the deferred tax assets, which are fully offset by a valuation allowance.

We file U.S. and state income tax returns with varying statutes of limitations. The tax years from 2001 to 2025 remain open to examination due to the carryover of unused NOL carryforwards and tax credits.

A reconciliation of our unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Balance at beginning of year	$ 10,903	$ 10,903
Decrease for tax positions of prior years	—	—
Increase based on tax positions related to current year	—	—
Balance at end of year	$ 10,903	$ 10,903

Due to our valuation allowance, the $10.9 million of unrecognized tax benefits would not affect the effective tax rate, if recognized. It is the Company’s practice to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2025 and 2024, we had no accrued interest and penalties related to

uncertain tax positions. We do not expect any material changes to the estimated amount of liability associated with our uncertain tax positions within the next 12 months.

On July 4, 2025, the One Big Beautiful Bill was enacted (“OBBBA”), introducing significant and wide-ranging changes to the U.S. federal tax system. Significant components include restoration of 100% accelerated tax depreciation on qualifying property including expansion to cover qualified production property. Another major aspect includes the return to immediate expensing of domestic research and experimental expenditures (“R&E”) which in some cases may include retroactive application back to 2021 for businesses with gross receipts of less than $31 million or accelerated tax deductions of R&E that was previously capitalized for larger businesses. The legislation also reinstates EBITDA-based interest deductions for tax purposes and makes several business tax incentives permanent. Less favorable business provisions include limitations on tax deductions for charitable contributions. The Company has analyzed the changes in the OBBBA and incorporated those that are relevant to the financial statements for the current year.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was enacted and signed into law in response to the COVID-19 pandemic. The CARES Act includes changes to the tax provisions that benefits business such as the Employee Retention Credit ("ERC"). The ERC provides an eligible employer with a tax credit that is allowed against certain employment taxes. We qualified for federal government assistance through the ERC provisions for the period between January 1, 2021 and September 30, 2021. We recognize government grants when there is reasonable assurance of compliance with grant conditions and receipt of the credits. For the year ended December 31, 2022, we recorded a one-time refund totaling $6.0 million, which was included in the consolidated balance sheets as prepaid expenses and other current assets, as well as in the consolidated statements of operations and comprehensive loss as an offset to the related employee expenses within research and development, general and administrative, and sales and marketing expenses. The one-time $6.0 million refund was received in the second quarter of 2023.

13. Subsequent Event

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. The Company has concluded that no subsequent events have occurred that require disclosure, except as included in Note 8.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 ("Exchange Act") as of December 31, 2025. Based on this evaluation, our principal executive and principal financial officers concluded that our disclosure controls and procedures were effective as of December 31, 2025.

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the U.S. and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the U.S., and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013).

Based on our assessment, management concluded that, as of December 31, 2025, our internal control over financial reporting was effective based on those criteria.

The independent registered public accounting firm that audited the consolidated financial statements that are included in this Annual Report on Form 10-K has issued an audit report on our internal control over financial reporting, which is included herein.

Changes in Internal Control Over Financial Reporting

There have been no significant changes in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Rule 10b5-1 Trading Plans

During the fourth quarter of 2025, none of the Company's directors or executive officers adopted or terminated any "Rule 10b5-1 trading arrangement" or any "non-Rule 10b5-1 trading arrangement" as each term is defined in Item 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this item will be contained in our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2025 (the "2025 Proxy Statement") in the sections titled: "Information Concerning the Board of Directors," "Information Concerning Executive Officers," "Delinquent Section 16(a) Reports," "Code of Ethics and Business Conduct," "Corporate Governance," "Insider Trading Policy," and "Report of the Audit Committee." Such information is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

Information required by this item will be contained in our 2026 Proxy Statement in the sections titled: "Director Compensation" and "Executive Compensation." Such information is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Information required by this item will be contained in our 2026 Proxy Statement in the sections titled: "Security Ownership of Certain Beneficial Owners and Management" and "Equity-Based Compensation Plan Information." Such information is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Information required by this item will be contained in our 2026 Proxy Statement in the sections titled: "Certain Relationships and Related Party Transactions" and "Board Independence." Such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Information required by this item will be contained in our 2026 Proxy Statement in the section titled: "Fees of the Independent Registered Public Accounting Firm." Such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES.

1. Consolidated Financial Statements.

   The consolidated financial statements and supplementary data set forth in Part II of the Annual Report on Form 10-K are included herein.

2. Consolidated Financial Statement Schedules.

   These schedules are omitted because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

3. Exhibits.

   The exhibits listed in the accompanying Exhibit Index are incorporated by reference herein or filed as part of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit	Document Description
3.1	Certificate of Incorporation, as amended through July 29, 2009 (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as Exhibit 3.1, filed on August 4, 2009)
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on June 30, 2011)
3.3	Certificate of Amendment to the Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on January 13, 2014)
3.4	Certificate of Amendment to the Certificate of Incorporation (incorporated by reference to our Company's Post-Effective Amendment to its Registration Statement on Form 8-A/A, filed on July 6, 2017)
3.5	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2018, as exhibit 3.6, filed on February 22, 2019)
3.6	Certificate of Amendment to the Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, as exhibit 3.1, filed on June 12, 2023)
3.7	Certificate of Amendment to the Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on June 18, 2024)
3.8	Certificate of Designation of Rights, Preferences and Privileges of Series A Convertible Preferred Stock of Heron Therapeutics, Inc., filed with the Secretary of State of the State of Delaware on August 11, 2025 (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on August 12, 2025)
3.9	Certificate of Designation of Series B Preferred Stock of Heron Therapeutics, Inc., filed with the Secretary of State of the State of Delaware on August 14, 2025 (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on August 15, 2025
3.10	Tax Benefit Preservation Plan, dated August 14, 2025, by and between Heron Therapeutics, Inc. and Computershare Trust Company N.A., which includes the Form of Certificate of Designation of Series B Preferred Stock as Exhibit A, Form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C (incorporated by reference to our Current Report on Form 8-K, as Exhibit 4.1, filed on August 15, 2025)
3.11	Amended and Restated Bylaws (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on February 8, 2019)
4.1	Common Stock Certificate (incorporated by reference to our Registration on Form S-3 (Registration No. 333-162968), as Exhibit 4.1, filed on November 6, 2009)
4.2	Form of Convertible Senior Unsecured Promissory Note (included in Exhibit 10.7)
4.3	Amended and Restated Certificate of Designation, Preferences, and Rights of Series A Preferred Stock (incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.C, filed on December 19, 2006)
4.4*	Description of the Registrant’s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
4.5	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on August 10, 2022)
10.1†	Amended and Restated 1997 Employee Stock Purchase Plan (incorporated by reference to our Form S-8 Registration Statement, as Exhibit 99.2, filed on June 30, 2023)
10.2†	Amended and Restated 2007 Equity Incentive Plan (incorporated by reference to our Form S-8 Registration Statement, as Exhibit 99.1, filed on June 30, 2023)
10.3†	Form of 2007 Equity Incentive Plan Stock Option Agreement
10.4†	Form of 2007 Equity Incentive Plan Restricted Stock Unit Agreement
10.5†	Form of Indemnification Agreement
10.6#+	Agreement of Sublease, dated as of September 23, 2024 by and between the Company and Crown Castle USA, Inc.
10.7	Note Purchase Agreement, dated August 8, 2025, by and among Heron Therapeutics, Inc. the purchasers party from time to time thereto and Rubric Capital Management LP (incorporated by reference to our Registration Statement on Form S-3, as Exhibit 10.1, filed on September 9, 2025)

10.8	Cooperation Agreement, dated August 8, 2025, by and among Heron Therapeutics, Inc. and Rubric Capital Management L.P. (incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on August 12, 2025)
10.9†	Executive Employment Agreement, dated April 3, 2023, by and between the Company and Craig Collard (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, as Exhibit 10.1, filed on August 14, 2023)
10.10†	Management Retention Agreement, dated June 6, 2023, by and between the Company and William Forbes (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, as Exhibit 10.3, filed on August 14, 2023)
10.11†	Management Retention Agreement, dated June 16, 2023, by and between the Company and Ira Duarte (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, as Exhibit 10.4, filed on August 14, 2023)
10.12†	Management Retention Agreement, dated April 28, 2025, by and between the Company and Mark Hensley (incorporated by reference to our Quarterly Report on Form 10-Q as Exhibit 10.3, filed on August 8, 2025)
10.13†	Form of Inducement Notice of Grant of Stock Options and Option Agreement (incorporated by reference to our Registration Statement on Form S-8, as Exhibit 99.3, filed on August 6, 2024)
10.14†	Form of Inducement Notice of Grant of Restricted Stock Units and Restricted Stock Unit Agreement (incorporated by reference to our Registration Statement on Form S-8, as Exhibit 99.4, filed on August 6, 2024)
10.15#	Working Capital Facility Agreement dated August 9, 2023, by and among the Company, the several banks and other financial institutions or entities from time to time party thereto, and Hercules Capital, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q, as Exhibit 10.10, filed on August 14, 2023)
10.16#	First Amendment to Working Capital Facility Agreement, dated as of February 13, 2025, by and among the Company, the several banks and other financial institutions or entities from time to time party thereto, and Hercules Capital, Inc. (incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on February 20, 2025)
10.17+	Second Amendment to Working Capital Facility Agreement, dated August 8, 2025, by and between Heron Therapeutics, Inc. and Hercules Capital, Inc., as administrative agent, collateral agent, and lender (incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on August 12, 2025)
10.18+*	Third Amendment to Working Capital Facility Agreement, dated January 30, 2026, by and between Heron Therapeutics, Inc. and Hercules Capital, Inc., as administrative agent, collateral agent, and lender
10.19+	Co-Promotion Agreement, dated as of January 5, 2024, by and between the Company and Crosslink Network, LLC (incorporated by reference to our Quarterly Report on Form 10-Q, as Exhibit 10.1, filed on May 7, 2024)
10.20+	Amendment No. 1 to Co-Promotion Agreement, dated as of January 5, 2024, by and between the Company and Crosslink Network, LLC (incorporated by reference to our Quarterly Report on Form 10-Q, as Exhibit 10.1, filed on November 12, 2024)
10.21+	Amendment No. 2 to Co-Promotion Agreement, dated as of January 5, 2024, by and between the Company and Crosslink Network, LLC (incorporated by reference to our Quarterly Report on Form 10-Q, as Exhibit 10.2, filed on November 12, 2024)
10.22+	Amendment No. 3 to Co-Promotion Agreement, dated as of January 5, 2024, by and between the Company and CrossLink Network, LLC (incorporated by reference to our Quarterly Report on Form 10-Q as Exhibit 10.1, filed on August 8, 2025)
10.23+	Amendment No. 4 to Co-Promotion Agreement, dated as of January 5, 2024, by and between the Company and CrossLink Network, LLC (incorporated by reference to our Quarterly Report on Form 10-Q as Exhibit 10.2, filed on August 8, 2025)
10.24+	Amendment No. 5 to Co-Promotion Agreement, dated as of January 5, 2024, by and between the Company and CrossLink Network, LLC (incorporated by reference to our Quarterly Report on Form 10-Q as Exhibit 10.4, filed on August 8, 2025)
10.25+	Amendment No. 6 to Co-Promotion Agreement, dated as of August 15, 2025, by and between the Company and Crosslink Network, LLC (incorporated by reference to our Quarterly Report on Form 10-Q as Exhibit 10.8, filed on November 4, 2025)
10.26+	Amendment No. 7 to Co-Promotion Agreement, dated as of August 15, 2025, by and between the Company and Crosslink Network, LLC

10.27+	Framework Agreement, dated August 6, 2025, by and between Heron Therapeutics, Inc. and Patheon Austria GmbH & Co KG (incorporated by reference to our Quarterly Report on Form 10-Q as Exhibit 10.1, filed on November 4, 2025)
10.28+	Office Lease Agreement, dated August 22, 2025, by and between Heron Therapeutics, Inc. and USEF HCG Fenton LLC (incorporated by reference to our Quarterly Report on Form 10-Q as Exhibit 10.7, filed on November 4, 2025)
19.1*	Insider Trading Policy
23.1*	Consent of Independent Registered Public Accounting Firm (WithumSmith+Brown, PC)
24.1*	Power of Attorney (included on the signature page hereto)
31.1*	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Compensation Recovery Policy (incorporated by reference to our Quarterly Report on Form 10-K, as Exhibit 97.1, filed on March 12, 2024
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith. The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

† Management contract or compensatory plan, contract or arrangement.

+ Certain information has been omitted from the exhibit in compliance with Item 601(b)(10) of Regulation S-K. The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.

Schedules to this Exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K under the Securities Act of 1933, as amended. A copy of any omitted schedule will be furnished to the SEC upon request.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

HERON THERAPEUTICS, INC.

DATE: February 26, 2026 BY: /s/ CRAIG COLLARD

Craig Collard
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Craig Collard as his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, with respect to this annual report and any and all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all the said attorney-in-fact and agent or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CRAIG COLLARD Craig Collard	Chief Executive Officer and Director *(Principal Executive Officer)*	February 26, 2026
/s/ IRA DUARTE Ira Duarte	Executive Vice President, Chief Financial Officer *(Principal Financial Officer)*	February 26, 2026
/s/ TOM CUSACK Tom Cusack	Director	February 26, 2026
/s/ SHARMILA DISSANAIKE Sharmila Dissanaike	Director	February 26, 2026
/s/ MICHAEL KASETA Michael Kaseta	Director	February 26, 2026
/s/ CRAIG JOHNSON Craig Johnson	Director	February 26, 2026
/s/ ADAM MORGAN Adam Morgan	Chairman of the Board of Directors	February 26, 2026
/s/ CHRISTIAN WAAGE Christian Waage	Director	February 26, 2026