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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended: **December 31, 2020**

☐ 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: **001-36329**

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	**26-1523233**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
490 Lapp Road, Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	(Zip Code)

(484) 395-2470
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol	Name of exchange on which registered
Common Stock, par value $0.01	**REPH**	**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. ☐

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

On the last business day of the most recently completed second fiscal quarter, the aggregate market value (based on the closing sale price of its common stock on that date) of the voting stock held by non-affiliates of the registrant was $93.0 million.

As of February 19, 2021, there were 31,012,003 shares of common stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2021 annual meeting of shareholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2020.

TABLE OF CONTENTS
Index

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K or the documents incorporated by reference herein regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would" "could," "should," "potential," "seek," "evaluate," "pursue," "continue," "design," "impact," "affect," "forecast," "target," "outlook," "initiative," "objective," "designed," "priorities," "goal," or the negative of such terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on assumptions and expectations that may not be realized and are inherently subject to risks, uncertainties and other factors, many of which cannot be predicted with accuracy and some of which might not even be anticipated.

The forward-looking statements in this Annual Report on Form 10-K and the documents incorporated herein by reference include, among other things, statements about:

- our estimates regarding expenses, future revenue, cash flow, capital requirements and timing and availability of and the need for additional financing;
- our ability to maintain or expand our relationships, profitability and contracts with our key commercial partners, including the impact of changes in consumer demand for the products we manufacture for our commercial partners;
- our ability to grow and diversify our business with new customers, including our ability to meet desired project outcomes with development customers;
- the extent to which the ongoing COVID-19 pandemic continues to disrupt our business operations and financial condition and the business operations and financial condition of our customers;
- our ability to operate under increased leverage and associated lending covenants; to pay existing required interest and principal amortization payments when due; and/or to obtain acceptable refinancing alternatives;
- the performance of third-party suppliers upon which we depend for Active Pharmaceutical Ingredients, or APIs, excipients, capsules, reagents, etc., and other third parties involved with maintenance of our facilities and equipment;
- our ability to obtain and maintain patent protection for applicable products and defend our intellectual property rights against third-parties;
- pharmaceutical industry market forces that may impact our commercial customers' success and continued demand for the products we produce;
- our ability to recruit or retain key scientific, technical, business development, and management personnel and our executive officers; and
- our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice, or cGMP, compliance and U.S. Drug Enforcement Agency, or DEA, compliance and other relevant regulatory authorities applicable to our business.

We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly under "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make. You should read this Annual Report on Form 10-K and the documents that we incorporate by

reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

Solely for convenience, tradenames referred to in this Annual Report on Form 10-K appear without the ® symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these tradenames. All trademarks, service marks and tradenames included or incorporated by reference in this Annual Report on Form 10-K are the property of their respective owners.

PART I

Item 1. Business

Overview

We are a dedicated contract development and manufacturing organization, or CDMO, solving complex formulation and manufacturing challenges for companies developing oral solid dose drug products. We leverage our formulation and development expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies and know-how for partners who develop and commercialize or plan to commercialize these products. In 2020, we launched our clinical trials support services capabilities, which includes preparation of clinical trial supplies, as well as specialized services dedicated to the development and Good Manufacturing Practices, or GMP, of high-potency products. We operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia, as well as a 24,000 square foot development, high-potency product and clinical packaging facility in Gainesville, Georgia that we opened in October 2018. We currently develop and/or manufacture the following key products with our key commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM and Verapamil SR, as well as supporting development stage products.

Our manufacturing and development capabilities include formulation, product development from formulation through clinical trial and commercial manufacturing, and specialized capabilities for solid oral dosage forms, extended release and controlled substance manufacturing, as well as high potency development and manufacturing. In a typical collaboration, we work with our partners to develop product candidates, or new formulations of existing product candidates, and may license certain intellectual property to such partners. We also typically exclusively manufacture and supply clinical and commercial supplies of these proprietary products and product candidates.

Our Strategy

The CDMO market is large and growing and is expected to continue to expand as outsourced penetration is seen due to biotechnology and pharmaceutical companies outsourcing more of their operations. We believe companies, which include our customers and prospective customers, generally prefer fewer, higher quality suppliers with specialized expertise in addressing their formulation and manufacturing challenges early in the development cycle. Our strategy for growth in this market includes:

- *Expand Existing Customer Relationships*. We maintain strong customer relationships with large pharmaceutical and biotechnology companies with established and stable pharmaceutical products. Our development-stage business also provides us the opportunity to provide services through the lifecycle of a product. Approximately 90% of our development customers have signed additional proposals for extension work, such as next step development proposals or additional batches. We view this repeat work as indicative of the level of confidence our existing customers have in our technical ability and reliable execution. We believe this pattern indicates potential for future growth and plan to leverage our current relationships for new business opportunities moving forward.

- *Diversify Our Customer Base.* We have taken, and continue to take, steps to diversify and expand our customer base. Over the last several years, we have increased our focus on business development, hired subject matter experts and established additional systems and processes to expand our offering of development-stage services to attract new customers. In 2020 we launched new clinical trial support services, or CTS, capabilities, and we launched a significant new commercial product tech transfer project. This strategy has resulted in adding 16 new customers over the past two years, and we expect to further expand our business with new customers in 2021.

- *Invest in our Manufacturing Capabilities.* We intend to continue investing in our facilities and infrastructure to maximize our utilization and support our customers' development and commercial manufacturing requirements.

- *Explore Acquisitions and Licensing*. We may drive growth through the acquisition of business capabilities, products, product lines, technologies and capabilities.

Our Competitive Strengths

We believe that the strong relationships we have with our commercial partners result from of our competitive strengths. In particular:

- *Our Operational Excellence*. We maintain a commitment to continually improve productivity and customer service levels and maintain excellent quality and regulatory compliance systems.

- *Focus on Specialized Markets*. We participate in specialized markets where significant technical expertise provides a competitive advantage. This includes differentiated drug delivery, controlled substance and complex formulation. Our core expertise is modified release oral solid dosage form development and manufacturing and custom release profile development, including for DEA controlled substance products. We developed extended, controlled and sustained release mechanisms and other intellectual property for several current commercial products.

- *Our Longstanding Relationships with Our Partners*. We maintain longstanding, collaborative relationships with our customers. We believe this allows us to leverage our extensive experience and deep knowledge of their business to better address our commercial partners' business and developmental goals.

- *Our Integrated Full-Service Development and Manufacturing Facilities.* We believe pharmaceutical companies generally prefer to engage with CDMOs that are able to work with a product throughout its lifecycle and have experienced a reliable track record of regulatory compliance and quality control first-hand. Our early-stage development and high-potency business feeds clinical and commercial manufacturing opportunities to our manufacturing business. We believe that by providing customers with a broad range of services from benchtop through commercial launch and supply, we can best support the needs of our customers throughout the lifecycle of their products. We provide fully-integrated and customized biomanufacturing services that support our customers from the early preclinical stage through commercial launch and supply. Our services are all supported by modern facilities designed to meet customer needs from early stage development to commercial supply.

- *Our Customer-Centric, Consultative Approach.* We are highly collaborative throughout the product lifecycle, guiding our commercial partners through the development process towards commercialization, including support and guidance on regulatory matters and chemistry, manufacturing and controls, or CMC, regulatory document preparation. In particular, we provide differentiated capabilities across a broad array of services that support the ability to serve our commercial partners through the entire development spectrum.

Services

We offer integrated solutions for formulation, analytical services, regulatory support, manufacturing, and packaging of both commercial and development stage oral solid dose drug products. Our two facilities are located just four miles apart in Gainesville, Georgia, allowing employees to seamlessly move from one facility to the other and leveraging the same support staff for facilities, quality, project management and information technology:

- Our 97,000 square foot manufacturing facility provides a full range of manufacturing capabilities from scale-up services to commercial manufacture.

- Our 24,000 square foot development and high-potency product facility focuses on development and clinical packaging.

Our end-to-end service capabilities allow our customers to start with us for early-phase projects and stay with us through late phase and commercial projects. Early-stage coordination with customers utilizing our development and high-potency product facility helps assure streamlined technology transfer for final scale up and manufacturing at our commercial manufacturing site.

Early phase capabilities:

- formulation, system design and engineering;
- stability programs;
- prototyping and pilot manufacturing;
- early stage quality assurance and quality control;
- analytical method development;
- nonclinical and early stage clinical development;
- pre-commercial manufacturing; and
- clinical trial labelling and packaging.

Late phase and commercial capabilities:

- process development and scale-up;
- prototype, pilot and commercial manufacturing;
- primary, secondary and tertiary packaging;
- analytical method development, validation and quality control with physical testing and analytical method capabilities; and
- clinical trial labelling and packaging.

Our Commercial Partners

We are party to agreements with each of our commercial partners governing the development, formulation and/or supply services we provide, as well as any applicable intellectual property licenses. Each commercial partner remains responsible for distributing, marketing and promoting their respective products. We are dependent on a small number of commercial partners, with our three largest customers (Novartis Pharma AG, or Novartis, Teva Pharmaceutical Industries, Inc., or Teva, and Lannett Company, Inc., or Lannett) having generated 91% of our revenues for the year ended December 31, 2020, of which, Novartis, Teva and Lannett generated 34%, 34% and 23% of our of our revenue, respectively.

The table below details the key products developed and/or manufactured with our key commercial partners:

Product	Indication	Territory	Revenue source	Commercial partner	Agreement term
Ritalin LA®	Attention Deficit Hyperactivity Disorder	Worldwide	Manufacturing	Novartis	Through December 31, 2023
Focalin XR®	Attention Deficit Hyperactivity Disorder	Worldwide, except Canada	Manufacturing	Novartis	Through December 31, 2023
Verelan PM®, SR & Verapamil PM	Hypertension	United States	Profit-sharing / manufacturing	Lannett	Through December 31, 2024
Verapamil SR	Hypertension	United States	Profit-sharing / manufacturing	Teva	Through December 31, 2024

Agreements with Key Commercial Partners

Teva

We are party to a License and Supply Agreement with Watson Laboratories, Inc., a subsidiary of Teva, or the Teva Agreement, pursuant to which we are the exclusive supplier of Verapamil SR to Teva. We own the NDA for Verapamil SR and, pursuant to the Teva Agreement, have granted Teva an exclusive license to commercialize and sell Verapamil SR in the United States. The Teva Agreement expires on December 31, 2024, after which it will renew for additional one-year periods unless terminated by either party. Under the Teva Agreement, Teva pays us a share of profits on sales of Verapamil SR.

Lannett

We are party to a License and Supply Agreement with Kremers Urban Pharmaceutical, Inc., a subsidiary of Lannett, or the Lannett Agreement, pursuant to which we supply Verelan PM and SR and Verapamil PM to Lannett. We own the new drug application, or NDA, related to Verelan and license commercialization rights to Lannett under the Lannett Agreement. The Lannett Agreement expires on December 31, 2024 and will renew thereafter for successive two-year periods. Under the Lannett Agreement, Lannett pays us a share of profits on sales of Verelan PM and SR and Verapamil PM. Lannett additionally pays us an annual license fee of $500,000 and, beginning in 2021, is obligated to reimburse to us 50% of the Prescription Drug User Act program fees associated with Verelan.

Novartis

We are party to a Manufacturing and Supply Agreement with Novartis, or the Novartis Agreement, pursuant to which we continued our long-standing relationship with Novartis as the exclusive global supplier to Novartis of Ritalin LA and Focalin XR capsules until December 31, 2023. The Novartis Agreement will renew automatically thereafter for successive one-year periods unless terminated by either party at least 24 months prior to December 31, 2023, or any subsequent one-year term thereafter. Novartis may terminate the Agreement immediately if (i) any governmental regulatory authority prevents Novartis from supplying the active pharmaceutical ingredients in the products and/or exporting, purchasing or selling the products; (ii) any product cannot be reasonably commercialized for medical, scientific or legal reasons; or (iii) we fail to comply with certain health, safety and environmental protection requirements. After the December 31, 2023, Novartis may terminate the Novartis Agreement upon 12 months' written notice in the event of any sale or divestment by us of our business or assets relating to the products.

Permits and Regulatory Approvals

We are required to comply with the regulatory requirements of various local, state, national and international regulatory bodies having jurisdiction in the countries or localities where we manufacture products or where our customers' products are distributed. In particular, we are subject to laws and regulations concerning research and development, testing, manufacturing processes, equipment and facilities, including compliance with cGMPs, labeling and distribution, import and export, and product registration and listing. As a result, our facilities are subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions.

We hold various licenses and registrations for our manufacturing activities. The primary licenses and registrations held are FDA Registrations of Drug Establishments and DEA Controlled Substance Registration. Due to certain U.S. state law requirements, we also hold certain state licenses for distribution activities throughout certain states. We also hold cGMP certifications for EU importation of products made in Gainesville for sale in the EU and an ANVISA certification for sale in Brazil. Compliance with these licensing and regulatory requirements is a key aspect of our business and, if there are changes in the regulations applicable to our business in the United States or other jurisdictions, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards or pay additional fees. This may require a change in our manufacturing techniques or additional capital investments in our facilities.

In certain of our commercial partnerships, our commercial partner is the product authorization holder for products that have been developed on behalf of the commercial partner. In other commercial partnerships, we are the authorization holder. When our commercial partner holds the relevant authorization from the FDA or other national regulator, we support this authorization by furnishing a letter of reference to the Drug Master File, or the chemistry, manufacturing and related data to the relevant regulator or sponsor to provide adequate manufacturing support in respect of the product. We generally update this information annually with the relevant regulator.

We hold the approved NDAs for Verelan SR and Verelan PM, which we license to Lannett and Teva, respectively. Verapamil SR and Verapamil PM are authorized generics.

Environmental and Safety Matters

Certain products manufactured by us involve the use, storage and transportation of toxic or hazardous material. Our operations are subject to extensive laws and regulations relating to the storage, handling, emissions, transportation and discharge of materials into the environment and the maintenance of safe working conditions. We maintain environmental and industrial safety and health compliance programs and training at our facilities.

Prevailing legislation tend to hold companies primarily responsible for the proper disposal of their waste even after transfer to third party waste disposal facilities. Other future developments, such as increasingly strict environmental, health and safety laws and regulations, and enforcement policies, could result in substantial costs and liabilities to us and could subject the handling, manufacture, use, reuse or disposal of substances or pollutants at our facilities to more rigorous scrutiny than at present.

Intellectual Property

We own several issued patents in the United States and several foreign patent applications for abuse resistant pharmaceutical compositions and methods of use related to Zohydro ER®, which provide patent protection through 2034, subject to any extensions or disclaimers. Although certain patents may have expired or may expire in the future, we believe there are other barriers to entry for our commercial partners and competition, including ownership of regulatory filings, NDAs, abbreviated new drug applications, or ANDAs, and drug master files, or DMFs, manufacturing trade secrets, proprietary dosage strengths, pricing limitations in various geographies, costs to revalidate with another supplier, maturity and life-cycle stage of products. We have acquired and developed and continue to acquire and develop knowledge and expertise and trade secrets in the provision of formulation, process development and manufacturing services. We intend to rely on a combination of patents and trade secrets, as well as confidentiality agreements and license agreements, to protect our proprietary know-how.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our current and future competitors include pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations.

We compete with contract pharmaceutical formulation and manufacturing companies such as Adare Pharma Solutions, Avara Pharmaceutical Services, Metrics Contract Services, Pharmaceutics International and Quotient Sciences, as well as other formulation, development and manufacture-related service providers.

Government Regulation

Governmental authorities in the United States at the federal, state and local level, and the equivalent regulatory authorities in other countries, extensively regulate the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, distribution, marketing, export and import of prescription drugs, such as those we are developing and manufacturing. Any drug products developed or manufactured by us are subject to pervasive and continuing regulation by the FDA, including compliance with Good Manufacturing Practices, or GMP, which impose procedural and documentation requirements. The FDA or other regulatory agencies can delay approval of a drug if our manufacturing facilities are not able to demonstrate compliance with GMPs, pass other aspects of pre-approval inspections (i.e., compliance with filed submissions) or properly scale up to produce commercial supplies. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies and are subject to periodic announced and unannounced inspections by the FDA and state agencies for compliance with GMP and other regulations. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from GMP and impose reporting and documentation requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with GMPs and other aspects of regulatory compliance. Failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of product approval, recall or seizure of the product or other voluntary, FDA-initiated or judicial action that could delay or prohibit further operations.

The Drug Supply Chain Security Act, or DSCSA, added new sections to the Federal Food, Drug & Cosmetic Act, or FD&C Act, that require manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers to take steps to identify and trace certain prescription drugs to protect against the threats of counterfeit, stolen, contaminated, or otherwise harmful drugs in the supply chain. Among other mandates, the DSCSA requires manufacturers and repackagers to affix or imprint a unique product identifier (comprised of a standardized numerical identifier, lot number, and expiration date of the product) on certain prescription drug packages in both a human-readable and on a machine-readable data carrier. The standardized numerical identifier is comprised of the product's corresponding National Drug Code combined with a unique alphanumeric serial number. A drug product is misbranded if it does not bear the product identifier as required by Section 582 of the FD&C Act. Section 582 also established several requirements relating to the verification of product identifiers.

Certain products that we manufacture are regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered and enforced by the United States Drug Enforcement Agency, or DEA. The DEA is concerned with the control and handling of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

The DEA regulates controlled substances by controlling them in five schedules. Schedule I and II controlled substances have a high potential for abuse, whereas Schedule III-V controlled substances have relatively decreasing potential for abuse. Therefore, the DEA imposes more stringent controls on Schedule I and II substances than Schedule III-V substances, including stricter security controls, quotas, and increased recordkeeping and reporting requirements. Certain of the products we manufacture and/or develop are regulated as Schedule II controlled substances. The DEA establishes annually an aggregate quota for how much certain controlled substances that we manufacture may be produced in total in the United States, based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce any Schedule II substance. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. In April 2018, the DEA proposed new guidelines aimed at strengthening the process for setting controls over diversion of controlled substances and making other improvements in the quota managements regulatory system for the production, manufacturing and procurement of controlled substances. Following a public comment period, the DEA published the final guidelines, which were substantially similar to the proposed guidelines, in July 2018. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including hydrocodone, which we use in the manufacture of certain products, by an average of 10% as compared to the 2018 quotas. The DEA has proposed further decreasing manufacturing quotas in 2020 for five of the six opioids, including hydrocodone, by an average of 28%. Together with reductions in morphine, this is a 53% decrease since 2016. In October 2019, the DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. The proposed regulations will establish use-specific quotas, including commercial sales, product development, transfer, replacement, and packaging. To decrease the risk of diversion and increase accountability, inventory allowances will be reduced, and procurement quota certifications will be required. In April 2020, in response to the COVID-19 pandemic, the DEA adjusted the established 2020 aggregate production quotas and assessment of annual needs for select Schedule II substances. The DEA took this action to ensure that the country has an adequate and uninterrupted supply of these substances during the public health emergency.

The DEA requires facilities that manufacture controlled substances to adhere to certain security requirements. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances and periodic reports must be made to the DEA, for example, distribution, acquisition, and inventory reports for Schedule I and II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or losses of any controlled substance and suspicious orders. In addition, special authorization and notification requirements apply to imports and exports.

The DEA requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring, or SOM, system includes well-defined due diligence, "know your customer" efforts and order monitoring.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Individual states also independently regulate controlled substances. We are subject to state regulation of distribution for these products. Failure to maintain compliance with applicable requirements, particularly where noncompliance results in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations, or take other enforcement action. In certain circumstances, violations could result in criminal prosecution.

In addition to DEA regulations, the U.S. government and state legislatures have enacted legislation and regulations intended to fight the opioid epidemic. In February 2016, the FDA released an action plan to address the opioid epidemic, which is part of a broader initiative led by the Department of Health and Human Services, which includes the release of a new Guideline for Prescribing Opioids for Chronic Pain, FDA's requirement of enhanced warnings and safety labeling, and institution of a class-wide REMs as a condition of approval. Further, the Comprehensive Addiction and Recovery Act, or CARA, was passed in 2016. CARA provides resources to improve state monitoring of controlled substances, including opioids. A Senate bill introduced in February 2018, known as CARA 2.0, would further limit initial prescriptions for opioids to three days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 would also increase civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids. More recently, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or Support Act, has been enacted. It provides for further regulation as well as funding for research and development of non-addictive painkillers. State legislatures have followed in the footsteps of the federal government in passing similar laws intended to limit prescription sales and quantities as well as increase the ability to monitor and regulate the manufacture and sale of opioids.

Corporate Information

We were incorporated under the laws of the Commonwealth of Pennsylvania in November 2007. Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355 and our telephone number is (484) 395-2470.

Acute Care Spin-Off

On November 21, 2019, we completed the spin-off of Baudax Bio, Inc., or Baudax Bio, to our shareholders. Baudax Bio consists of our former Acute Care business. The transaction was completed through a pro rata distribution of 100% of the common stock of Baudax Bio to our shareholders of record as of the close of business on November 15, 2019. Each of our shareholders received one share of Baudax Bio's common stock, for every two and one-half shares of our common stock. Additionally, we contributed $19 million of cash to Baudax Bio in connection with the separation. For additional information on the spin-off of Baudax Bio please read note 3 to our consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K.

Employees and Human Capital Resources

Employees

As of December 31, 2020, we had 185 full-time employees. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Diversity & Inclusion

We are fundamentally committed to creating and maintaining a work environment in which employees are treated fairly, with dignity, decency, respect and in accordance with all applicable laws. We strive to create a professional work environment that is free from all forms of harassment, discrimination and bullying in the workplace, including sexual harassment and any form of retaliation. We are an equal opportunity employer and we strive to administer all human resources actions and policies without regard to race, color, religion, sex, national origin, ethnicity, age, disability, sexual orientation, gender identification or expression, past or present military or veteran status, marital status, familial status, or any other status protected by applicable law. Our management team and employees are expected to exhibit and promote honest, ethical, and respectful conduct in the workplace. All employees must adhere to a code of conduct that sets standards for appropriate behavior and are required to attend annual training to help prevent, identify, report, and stop any type of discrimination and harassment. Our recruitment, hiring, development, training, compensation, and advancement at our company is based on qualifications, performance, skills, and experience without regard to gender, race and ethnicity.

Competitive Pay & Benefits

We provide robust compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs include potential annual discretionary bonuses, a 401(k) Plan, healthcare and insurance benefits, flexible spending accounts, paid time off, various leave programs and flexible work schedules, among others. In addition, we offer every full-time employee, both exempt and non-exempt, the benefit of equity ownership in the company through stock option grants. We have also used targeted equity-based grants with vesting conditions to facilitate retention of personnel, particularly those with critical drug development skills and experience.

Safety

The safety, health and wellness of our employees is a top priority. In response to COVID-19, we have implemented enhanced safety protocols including shift work scheduling to reduce number of people in the facility, requirements for the wearing of masks and for social distancing, increased cleaning procedures and readily available hand sanitizer. These protocols are designed to comply with health and safety standards as required by federal, state, and local government agencies, taking into consideration guidelines of the Centers for Disease Control and Prevention and other public health authorities. In addition, we have provided work-at-home arrangements for employees who are able to do so.

Available Information

Our website address is www.recrocdmo.com. Our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements filed or furnished with the Securities and Exchange Commission, or SEC, are available free of charge through our website. We make these materials available through our website as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the SEC. The reports filed with the SEC by our executive officers and directors pursuant to Section 16 under the Exchange Act are also made available, free of charge on our website, as soon as reasonably practicable after copies of those filings are provided to us by those persons. These materials can be accessed through the "Investor Relations" section of our website. The information contained in, or that can be accessed through, our website is not part of this Report.

Item 1A. Risk Factors

Summary of Risk Factors

The risk factors summarized and detailed below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. These are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

Risks Related to Our Business and Industry

- Our revenues are dependent on a small number of commercial partners, and the loss of any one of these partners, or a decline in their orders, may adversely affect our business.
- Our failure to obtain new customer contracts or renew existing contracts may adversely affect our business.
- The COVID-19 pandemic has negatively impacted, and may continue to negatively impact, our business operations and financial results.
- Failure to obtain manufacturing components, supplies and related materials from third-party manufacturers, including due to implications stemming from the COVID-19 pandemic, could affect our ability to manufacture and deliver our products.
- Our and our customers' failure to receive or maintain regulatory approval for product candidates or products could negatively impact our revenue and profitability.
- We depend on spending and demand from our customers for our contract manufacturing and development services and any reduction in spending or demand could have a material adverse effect on our business.

- Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.
- The consumers of the products we manufacture for our customers may significantly influence our business, results of operations and financial condition.
- Our operating results may fluctuate significantly.
- We have a history of losses. If we cannot maintain profitability and secure additional business, we may have to raise additional capital.
- We have incurred significant indebtedness, which could adversely affect our business.
- We may not be entitled to forgiveness of our recently received Paycheck Protection Program Loan, and our application for the Paycheck Protection Program Loan could in the future be determined to have been impermissible or could result in damage to our reputation.
- We operate in a highly competitive market and competition may adversely affect our business.
- Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.
- If we fail to meet the stringent requirements of governmental regulation in the manufacture of pharmaceutical products, we could incur substantial costs and a reduction in revenues.
- If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.
- Technological change may cause our offerings to become obsolete over time. A decrease in our customers' purchases of our offerings could have a material adverse effect on our business, results of operations and financial condition.
- We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.
- We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business.
- Our future success depends on our ability to retain our key executives as well as to attract, retain and motivate other qualified personnel.
- Our employees, partners, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- We may face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- We incur increased costs and demands upon our management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.
- The security of our information technology systems may be compromised in the event of system failures, unauthorized access, cyberattacks or a deficiency in our cybersecurity, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

- If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

- Potential indemnification obligations to Baudax Bio or a refusal of Baudax Bio to indemnify us pursuant to agreements executed in the spin-off could materially adversely affect us.

Risks Related to Our Intellectual Property

- Litigation involving patents, patent applications and other proprietary rights is expensive and time-consuming. If we are involved in such litigation, it could interfere with our business.

- Generic competitors can challenge the U.S. patents protecting our commercial partners' product candidates by filing an ANDA or an NDA for a generic or a modified version of our commercial partners' product candidates.

- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

- Our ability to manufacture products for our commercial partners may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Risks Relating to Our Securities

- The market price and trading volume of our common stock have been and may continue to be volatile, which could result in rapid and substantial losses for our shareholders.

- The concentration of our capital stock ownership with our directors and their affiliated entities and our executive officers will limit shareholders' abilities to influence certain corporate matters.

- Some provisions of our charter documents and Pennsylvania law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders, and may prevent attempts by our shareholders to replace or remove our current management.

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 3 of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. All references and risks related to the launch, commercialization or sale of any of our product candidates are predicated on such product candidates receiving the requisite marketing and regulatory approval in the United States and applicable foreign jurisdictions.

Risks Related to Our Business and Industry

Our revenues are dependent on a small number of commercial partners, and the loss of any one of these partners, or a decline in their orders, may adversely affect our business.

We are dependent on a small number of commercial partners, with our three largest customers (Novartis Pharma AG, or Novartis, Teva Pharmaceutical Industries, Inc., or Teva, and Lannett Company, Inc.) having generated 91% of our revenue for the year ended December 31, 2020, of which Novartis and Teva each generated 34% of our revenue and Lannett generated 23% of our revenue. If any one or more of these commercial partners faces increasing or new competition in their market, adjusts pricing, significantly reduces their purchasing volume or experiences financial difficulties such as bankruptcy, our revenues could be adversely affected. For example, we have recently observed lower end-user demand for certain of the commercial products we manufacture for our customers, which we believe is due to the effects of COVID-19 and has led to a reduction of certain of our customer's demand for our manufacturing services.

Our profit sharing, royalty, and manufacturing revenues also depend on the ability of our commercial partners to effectively market and sell their products to their customers. A commercial partner may choose to devote its efforts to its other products or reduce or fail to devote the necessary resources to provide effective sales and marketing support for the products we manufacture and supply. Furthermore, the acquisition of or change in strategy by one of our customers could impact projects we are currently working on or planning to work on in the future. Our commercial partners face competition from other pharmaceutical companies for sales of products to end users.Competition from sellers of generic drugs is a major challenge for our commercial partners, and the loss or expiration of intellectual property rights for the products we manufacture can have a significant adverse effect on their sales volume and price. In addition, as pharmaceutical product pricing faces scrutiny by governments, legislative bodies and enforcement agencies, our commercial partners may lower their prices or adopt cost-savings measures which could be passed on to us or otherwise impact our profit-sharing revenues. Further, any commercial partner may divest the product we manufacture for them in whole or in certain markets, which may involvetermination of our contract with such partner or the assignment of such contract to a new partner who may not be as effective at selling or commercializing such product. These pricing changes and any significant reduction, delay or cancellation of orders from our commercial partners could adversely affect our revenues.

Our failure to obtain new customer contracts or renew existing contracts may adversely affect our business.

Our agreements with Teva and Lannett expire on December 31, 2024, and our agreement with Novartis expires on December 31, 2023. If any of these commercial partners fail to renew their contract, our revenues could be adversely affected. We continually seek to renew existing customer contracts and secure new contracts, which subjects us to potentially significant pricing pressures. While our preferred practice is to renegotiate new or extended agreements prior to expiration, in the event we are unable to replace existing contracts in a timely manner or at all, or are forced to accept terms, including pricing terms, less favorable to us, the our business, results of operations and financial condition could be materially and adversely affected.

The COVID-19 pandemic has negatively impacted, and may continue to negatively impact, our business operations and financial results.

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China. COVID-19 spread to other countries, including the United States, and was declared to be a pandemic by the World Health Organization on March 11, 2020. Efforts to contain the spread of COVID-19 have intensified, and many countries throughout the world, including the United States, have implemented travel restrictions, social distancing guidelines and quarantine requirements. A number of states, including Georgia, where our Gainesville manufacturing facilities are located, have enacted mandatory shutdowns for certain businesses and strict quarantine measures for individuals displaying symptoms of the virus.

While the COVID-19 pandemic has not had a significant impact on our ability to conduct our business due to our designation as an essential business and our facilities remain open at this time, we are unable to host site visits by potential customers or engage in other in-person marketing activities, which may result in decreased demand for our products and could materially and adversely affect our business. We have experienced slower than expected new project starts, which we believe is primarily attributable to the COVID-19 pandemic and the related concerns of our customers, resulting in delays in plans for their development services.

The continued spread of COVID-19 has led to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets in the future. The continued spread of COVID-19 may continue to cause economic disruptions of indeterminable duration and intensity or cause other unpredictable events, each of which could materially and adversely affect our business. We may need to reduce our workforce or implement additional cost-mitigating strategies, which could materially affect our ability to manufacture and deliver our products.

The impact of the COVID-19 pandemic remains unknown, and the extent to which the pandemic ultimately impacts our financial results will depend on uncertain and unpredictable future developments, including the emergence of new information concerning the severity of the pandemic and additional government or private actions to contain the virus or treat its impact, among others. Moreover, the COVID-19 pandemic has had indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that COVID-19 or any other pandemic harms the global economy generally. Therefore, at this time we cannot predict the extent to which our results of operations, financial condition or liquidity will ultimately be impacted, and we will continue to monitor the situation closely.

Failure to obtain manufacturing components, supplies and related materials from third-party manufacturers, including due to implications stemming from the COVID-19 pandemic, could affect our ability to manufacture and deliver our products.

We rely on third-party manufacturers to supply many of our manufacturing components, supplies and related materials, which in some instances are supplied from a single source. Prolonged disruptions in the supply of any of our key manufacturing components, supplies and related materials, including due to the sweeping effects the COVID-19 pandemic has had on commercial activity throughout the world; difficulty implementing replacement materials or new sources of supply; or a significant increase in the prices of manufacturing components, supplies and related materials could have a material adverse effect on our operating results, financial condition or cash flows. In particular, manufacturing problems may occur with these suppliers, and if a supplier provides us with manufacturing components, supplies and related materials that are deficient or defective or if a supplier fails to provide us with such materials or supplies in a timely manner, we may have limited ability to find appropriate substitutes or otherwise meet required specifications and deadlines. Moreover, we could experience inventory shortages if we are required to use an alternative supplier on short notice, which also could lead to manufacturing components, supplies and related materials being purchased on less favorable terms than we have with our regular suppliers. If such problems occur, we may not be able to manufacture our products profitably or on time, which could harm our reputation and have a material adverse effect on our business.

Several of our manufacturers and suppliers conduct business internationally. Travel bans and "stay-at-home" orders may affect the ability of these companies to conduct commercial activity, which could disrupt our supply chain and negatively impact our operations. If our suppliers are unable to provide the products and manufacturing components necessary to conduct our business, we may experience inventory shortages, and could be required to use an alternative supplier on short notice and enter into agreements on less favorable terms than we have with our regular suppliers. We also rely on third parties for the maintenance of our facilities and equipment. The COVID-19 pandemic poses the risk that any of the third parties on which we rely may be prevented from conducting normal business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities.

Our and our customers' failure to receive or maintain regulatory approval for product candidates or products could negatively impact our revenue and profitability.

Our business materially depends upon the regulatory approval of the products we manufacture. As such, if we or our customers experience a delay in, or failure to receive, approval for any of their product candidates or fail to maintain regulatory approval of products, our revenue and profitability could be adversely affected. For example, in 2019, a customer preparing for commercial launch scale-up received a complete response letter from the FDA and, as a result, cancelled their anticipated commercial launch orders, which impacted our anticipated revenue for 2020. Additionally, if the FDA or a comparable foreign regulatory authority does not approve of our facilities for the manufacture of a customer product or if it withdraws such approval in the future, our customers may choose to identify alternative manufacturing facilities and/or relationships, which could significantly impact our ability to expand our capacity and capabilities.

We depend on spending and demand from our customers for our contract manufacturing and development services and any reduction in spending or demand could have a material adverse effect on our business.

The amount that our customers spend on the development and manufacture of their products or product candidates, particularly the amount our customers choose to spend on outsourcing these services to us, substantially impacts our revenue and profitability. The outcomes of our customers' research, development and marketing also significantly influence the amount that our customers choose to spend on our services and offerings. Our customers determine the amounts that they will spend on our services based upon, among other things, the clinical and market success of their products, available resources, access to capital and their need to develop new products, which, in turn, depend upon a number of other factors, including their competitors' research, development and product initiatives and the anticipated market for any new products, as well as clinical and reimbursement scenarios for specific products and therapeutic areas. Further, increasing consolidation in the pharmaceutical industry may impact such spending, particularly in the event that any of our customers choose to develop or acquire integrated manufacturing operations. Any reduction in customer spending on development and related services as a result of these and other factors could have a material adverse effect on our business, results of operations and financial condition.

Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.

The manufacturing services we offer are highly complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single manufacturing run or a series of runs, requiring the destruction of products, or could halt manufacturing operations altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost drug substance, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

The consumers of the products we manufacture for our customers may significantly influence our business, results of operations and financial condition.

We depend on, and have no control over, consumer demand for the products we manufacture for our customers. Consumer demand for our customers' products could be adversely affected by, among other things, delays in health regulatory approval, the inability of our customers to demonstrate the efficacy and safety of their products, the loss of patent and other intellectual property rights protection, the emergence of competing or alternative products, including generic drugs, the degree to which private and government payment subsidies for a particular product offset the cost to consumers and changes in the marketing strategies for such products. If the products we manufacture for our customers do not gain market acceptance, our revenues and profitability may be adversely affected.

Third party national data demonstrates that there has been a meaningful impact of COVID-19 on the reduction of total prescriptions filled by patients across most therapeutic areas, including chronic cardiovascular and pediatric medications. We continue to see the COVID-19 pandemic resulting in lower end-user demand for our manufacturing services and inventory rebalancing by our commercial partners with respect to these products, especially since the duration of the COVID-19 pandemic and its impacts are not predictable at this time. These impacts have had and may continue to have an adverse effect on our business, results of operation and financial condition.

We believe that continued changes to the healthcare industry, including ongoing healthcare reform, adverse changes in government or private funding of healthcare products and services, legislation or regulations governing the privacy of patient information or patient access to care, or the delivery, pricing or reimbursement of pharmaceuticals and healthcare services or mandated benefits, may cause healthcare industry participants to purchase fewer services from us or influence the price that others are willing to pay for our services. Changes in the healthcare industry's pricing, selling, inventory, distribution or supply policies or practices could also significantly reduce our revenue and profitability.

Our operating results may fluctuate significantly.

Our operating results may be subject to quarterly and annual fluctuations. Our operating results will be affected by numerous factors, including:

- fluctuations in the revenues, including the loss of a major commercial partner or product;
- the timing of purchasing order patterns, safety stock methodology and habits of our commercial partners;
- unsuccessful execution, postponement or cancellation of anticipated formulation, development and manufacturing services related to customer projects,
- variations in the level of expenses related to our production volumes and development programs;
- any intellectual property infringement lawsuit in which we may become involved;

- CDMO or pharmaceutical competitors that introduce new products or take increased positions that may emerge and reduce market share for our existing customer/partner products;
- our execution of any additional collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- our acquisition, divestiture, spin-off or in-licensing of new technologies or assets.

Due to the various factors mentioned above, and others, the results of any prior quarterly period should not be relied upon as an indication of our future operating performance. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

We have a history of losses. If we cannot maintain profitability and secure additional business, we may have to raise additional capital.

We have incurred significant losses of $27.5 million, $18.6 million and $79.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $234.4 million. We have financed our operations through the issuance of debt and equity and through operations, and as of February 19, 2021, we had $100.0 million of outstanding term loans under our current credit facility with Athyrium Opportunities III Acquisition LP, or Athyrium. Although it is difficult to forecast all of our future liquidity requirements, we believe that our cash and cash equivalents on hand combined with our projected cash receipts from services generated under our customer contracts will be sufficient to fund our operations beyond one year after the date our financial statements are issued. In addition, in the event a customer timely cancels its commitments prior to our initiation of manufacturing services, we may be required to refund some or all of the advance payments made to us under those canceled commitments, which would have a negative impact on our liquidity and future revenue.

In the event we are unable to maintain sufficient business to support our current operations, we may need to raise additional capital in the future. There can be no assurance that equity financing will be available on acceptable terms or at all. Our ability to raise additional capital in the equity markets to fund our future operations is dependent on a number of factors, including, but not limited to, the market demand for our common stock. The market demand or liquidity of our common stock is subject to a number of risks and uncertainties, including but not limited to, our financial results and economic and market conditions. In addition, even if we are able to raise additional capital, it may not be at a price or on terms that are favorable to us.

We have incurred significant indebtedness, which could adversely affect our business.

As of February 19, 2021, we had an outstanding balance under our credit agreement with Athyrium of $100.0 million. Our indebtedness could have important consequences to our shareholders. For example, it:

- increases our vulnerability to adverse general economic or industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate;
- reduces proceeds we may receive as a result of any sale;
- makes us more vulnerable to increases in interest rates, as borrowings under our credit agreement with Athyrium are at variable rates;
- limits our ability to obtain additional financing or refinancing in the future for working capital or other purposes; and
- places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Any of the above-listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with Athyrium also contains certain financial and other covenants, including a minimum liquidity requirement and maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. The credit agreement provides for certain mandatory prepayment events, including with respect to the proceeds of asset sales, extraordinary receipts, debt issuances and other specified events, based on the terms of the credit agreement with Athyrium. Any failure to comply with the terms, covenants and conditions of the credit agreement may limit our ability to draw upon additional tranches of term loans and may result in an event of default under such agreement, which could have a material adverse effect on our business, financial condition and results of operation.

We may not be entitled to forgiveness of our recently received Paycheck Protection Program Loan, and our application for the Paycheck Protection Program Loan could in the future be determined to have been impermissible or could result in damage to our reputation.

On May 12, 2020, we received loan proceeds of approximately $4.4 million pursuant to the Paycheck Protection Program, or PPP, under the Coronavirus Aid, Relief and Economic Security Act of 2020, or CARES Act administered by the Small Business Administration, or SBA. We used the proceeds from the loan, or PPP Loan, to retain current employees, maintain payroll and make lease and utility payments. The Loan is evidenced by a promissory note issued by PNC Bank, dated as of May 12, 2020, which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The PPP Loan is scheduled to mature on May 12, 2022, or the Maturity Date, bears interest at a rate of 1.00% per annum, and is subject to the standard terms and conditions applicable to loans administered by the SBA under the CARES Act. On May 18, 2020, we prepaid $1.1 million of the amount due under the PPP Loan, which was within the safe harbor time period for repayment established by the Small Business Administration and/or Treasury Department. Certifications made with respect to loan amounts repaid during this safe harbor period are deemed to have been made in good faith.

Commencing December 15, 2020, we are required to pay regular monthly payments in an amount equal to one month's accrued interest under the PPP Loan. All interest which accrues during the initial six months of the loan period will be deferred and payable on the Maturity Date. The amounts outstanding under the PPP Loan may be prepaid by us at any time prior to maturity without penalty. Under the CARES Act, as amended in June 2020, loan forgiveness is generally available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the 24-week period beginning on the date of the first disbursement of the PPP Loan. The amount of the PPP Loan eligible to be forgiven may be reduced in certain circumstances, including as a result of certain headcount or salary reductions. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest. We applied for loan forgiveness on October 6, 2020. We cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, the maintenance of our workforce, our need for additional funding to continue operations, and our ability to access alternative forms of capital in the current market environment in light of the uncertainty resulting from the COVID-19 pandemic. Following this analysis, we believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the CARES Act. The certification described above did not contain any objective criteria and is subject to interpretation.

On April 23, 2020, the SBA issued new guidance that questioned whether a public company with substantial market value and access to capital markets would qualify to participate in the PPP. The SBA guidance further indicated that borrowers "must make [the need] certification in good faith, taking into account their current business activity and their ability to access other sources of liquidity sufficient to support their ongoing operations in a manner that is not significantly detrimental to the business." Subsequently, on April 29, 2020 the SBA issued guidance that it will review all PPP loans of more than $2 million, including our PPP Loan, following the lender's submission of the borrower's loan forgiveness application.

Under the PPP, all or a portion of the PPP Loan is eligible for forgiveness if the SBA determines that we were eligible to apply for and receive the PPP Loan, that we used the loan proceeds for eligible expenses, and that we otherwise satisfied the PPP requirements. While we believe we are eligible for the PPP Loan, in the event SBA determines that we were not eligible for the PPP, it is possible we would be required to repay the PPP Note on an accelerated basis, rather than over the two years provided under the PPP Note, and at a higher interest rate than 1.000% per annum. If we receive an adverse finding in any audit related to the PPP Note, some or all of the PPP Note might not be forgiven and we could be required to return or repay some or all of the PPP Note, together with interest on the loan, which could reduce our liquidity, and potentially subject us to fines and penalties.

We operate in a highly competitive market and competition may adversely affect our business.

We operate in a market that is highly competitive. Our competition in the contract manufacturing market includes full-service contract manufacturers and large pharmaceutical companies offering third-party manufacturing services to fill their excess capacity. One of our competitors in the production of verapamil had faced shortage and supply issues in recent years and our sales of verapamil had increased as a result but has since returned to the manufacturing market for verapamil. This has resulted in a decrease in customer ordering patterns and the loss of Verapamil SR market share by our commercial partner, although the product has recovered to an observed percentage of approximately 50% market share. While total unit volumes have declined during COVID-19, relative market share has remained steady for both parties. This has negatively impacted both anticipated manufacturing volumes and profit sharing for this key customer. We may also compete with the internal operations of those pharmaceutical companies that choose to source their product offerings internally. In addition, most of our competitors may have substantially greater financial, marketing, technical or other resources than we do. Moreover, additional competition may emerge, particularly in lower-cost jurisdictions such as India and China, which could, among other things, result in a decrease in the fees paid for our services, which may adversely affect our results of operations and financial condition.

Our business, financial condition, and results of operations are subject to risks arising from the international scope of our manufacturing and supply relationships.

Some of our customers source raw materials outside the United States. As such, we are subject to risks associated with such international manufacturing relationships, including:

- unexpected changes in regulatory requirements;
- problems related to markets with different cultural biases or political systems;
- longer payment cycles and shipping lead-times;
- increased risk relating to the transport of products internationally, including damage to our customers' API, shipment delays relating to the import or export of our products or the delivery of products by means of additional third-party vendors;
- difficulties importing or exporting supplies or products;
- unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease (including, for example, the recent coronavirus outbreak);
- compliance with the U.S. Foreign Corrupt Practices Act and other laws and regulations governing international trade;
- changes to U.S. and foreign trade policies, including the enactment of tariffs on goods imported into the United States; and
- imposition of domestic and international customs and tariffs, withholding or other taxes, including any value added taxes.

Additionally, we are subject to periodic reviews and audits by governmental authorities responsible for administering import/export regulations. To the extent that we are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties, and increased duties on products imported into the United States.

Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our customers product candidates and services and assuring the safety and efficacy of their product candidates. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our future products, which may result in difficulty in successfully launching product candidates and the loss of sales, which could have a material adverse effect on our business, financial condition, and results of operations.

Our development and formulation services projects are typically for a shorter term than our manufacturing projects, and any failure by us to maintain an adequate volume of development and formulation services projects, including due to lower than expected success rates of the products for which we provide services, could have a material adverse effect on our business, results of operations and financial condition.

Our pharmaceutical development services business contracts are generally shorter in term than our manufacturing contracts and typically require us to provide development services within a designated scope. Since our development and formulation services focus on products that are still in developmental stages, their viability depends on the ability of such products to reach their respective subsequent development phases. In many cases, such products do not reach subsequent development phases and, as a result, the profitability of the related pharmaceutical development service project may be limited. Even if a customer wishes to proceed with a project, the product we are developing on such customer's behalf may fail to receive necessary regulatory approval or may have its development hindered by other factors, such as the development of a competing product.

If we are unable to continue to or timely obtain new projects from existing and new customers, our development and formulation services business could be adversely affected. Furthermore, although our development and formulation services business may act as a pipeline for our manufacturing services business, we cannot predict the conversion rate of our development and formulation services projects to commercial manufacturing services projects, or how successful we will be in winning new projects that lead to a viable product. As such, an increase in the turnover rate of our development and formulation services projects may not benefit our manufacturing services business at a later time.

In addition, our backlog is subject to a number of risks and uncertainties, including risk that a customer timely cancels its commitments, the risk that a customer may experience delays in its program(s) or otherwise, which could result in the postponement or cancellation of anticipated formulation, development and manufacturing services revenue. There is risk that our business development efforts may not materialize as quickly as we have projected, that we may not successfully execute on all customer projects, any of which could have a negative impact on our liquidity, reported backlog and future revenue. Further, the discontinuation of a project as a result of our failure to satisfy a customer's requirements may also affect our ability to obtain future projects from such customer, as well as from new customers. Any failure by us to maintain a high volume of development and formulation services projects could have a material adverse effect on our business, results of operations and financial condition.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of pharmaceutical products, we could incur substantial costs and a reduction in revenues.

We are required to maintain compliance with cGMP, and our manufacturing facilities are subject to inspections by the FDA and other global regulators to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA and acceptance of the change by the FDA prior to release of our manufactured products. Because we produce multiple products at our manufacturing facilities, there are increased risks associated with cGMP compliance. On August 12, 2019, following a six-day pre-approval inspection of our primary manufacturing facility, the FDA issued a Form 483 containing two observations relating to a documentation issue and incomplete investigation. We have promptly responded to these observations as a part of our ongoing obligations under the FDA's quality system regulation and have implemented corrective and preventative actions to ensure these issues do not occur in the future. While we remain committed to continuous improvement and strengthening our quality system and ensuring that all aspects of the system are in full compliance, we can provide no assurance that we will not encounter future inspections resulting in observations not acceptable by the FDA.

Our inability to demonstrate ongoing cGMP compliance could require us to engage in additional lengthy and expensive remediation efforts, withdraw or recall products and/or interrupt commercial supply of any products. Any delay, interruption or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product as a result of a failure of our facilities to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our relationships with our commercial partners, which would substantially harm our business, prospects, operating results and financial condition. Any ongoing or additional findings of non-compliance could also increase our costs and cause us to lose revenue from manufactured products, which could be seriously detrimental to our business, prospects, operating results and financial condition.

Additionally, our manufacturing activities are subject to the Controlled Substances Act and the regulations of the DEA. Accordingly, we must adhere to a number of requirements with respect to controlled substances, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements can result in an enforcement action that could have a material adverse effect on our business, financial condition, operating results and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities, including equivalent regulatory authorities in other countries, for compliance with cGMP regulations and adherence to commitments made in the NDA or the application for marketing authorization. If we, or a regulatory authority, discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by the equivalent regulatory authorities in other countries.

We have manufactured opioid products and may manufacture them in the future, which are subject to additional regulation by state and federal law enforcement and other regulatory agencies.

We have manufactured opioid products containing hydrocodone and may manufacture opioids in the future. The U.S. government and state legislatures have prioritized combatting the growing misuse and addiction to opioids such as hydrocodone and have enacted legislation and regulations as well as other measures intended to fight the opioid epidemic. Addressing prescription drug abuse is a priority for the current U.S. administration and the FDA and is part of a broader initiative led by the Department of Health and Human Services. Overall, there is greater scrutiny of entities involved in the manufacture, sale and distribution of opioids. These initiatives, existing regulations, and any negative publicity related to opioids may have a material impact on our business and our ability to manufacture opioid products.

Opioids are controlled substance regulated by the DEA. The amount of Schedule II substances that can be obtained is limited by the CSA and DEA regulations. In November 2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the U.S. in calendar year 2018 by 20%. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas; and DEA has proposed further decreasing manufacturing quotas in 2020 for five of the six opioids (fentanyl, hydrocodone, hydromorphone, oxycodone, oxymorphone), by an average of 28%. Together with reductions in morphine, this is a 53% decrease since 2016. In October 2019, the DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. The proposed regulations will establish use-specific quotas, including commercial sales, product development, transfer, replacement, and packaging. To decrease the risk of diversion and increase accountability, inventory allowances will be reduced, and procurement quota certifications will be required. If limited supply of opioids impacts demand for products of our potential partners, our future revenues may be adversely impacted. In addition to DEA regulations, the U.S. government and states have enacted other laws that seek to promote improved monitoring of opioids and to increase funding for research and development of non-addictive painkillers. Legislation has also been proposed that would further limit the ability to sell and prescribe opioids. These efforts may result in an additional reduction of demand for opioid products or government action against us if we fail to comply with these laws and could have a material adverse effect on our business.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our operations involve the controlled use of hazardous materials and chemicals. We are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of hazardous materials and chemicals. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Even if we comply with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials or chemicals. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our contract manufacturing operations, which could materially harm our business, financial condition and results of operations.

We may not be able to successfully offer new services.

In order to successfully compete, we will need to offer and develop new services. Without the timely introduction of enhanced or new services, our services and capabilities may become obsolete over time, in which case, our revenues and operating results would suffer. The related development costs may require a substantial investment before we can determine their commercial viability, and we may not have the financial resources to fund such initiatives.

In addition, the success of enhanced or new services will depend on several factors, including but not limited to our ability to:

- properly anticipate and satisfy customer needs, including increasing demand for lower cost services;
- enhance, innovate, develop and manufacture new offerings in an economical and timely manner;
- differentiate our deliverables from competitors' offerings;
- meet quality requirements, authorization requirements, and other regulatory requirements of government agencies; and
- avoid infringing the proprietary rights of third parties.

Even if we were to succeed in creating enhanced or new services, those services may not result in commercially successful offerings or may not produce revenues in excess of the costs of development and capital investment and may be quickly rendered obsolete by changing customer preferences or by technologies or features offered by our competitors. In addition, innovations may not be accepted quickly in the marketplace due to, among other things, entrenched patterns of clinical practice, the need for regulatory clearance and uncertainty over market access or government or third-party reimbursement. If we are not able to offer new services and effectively compete, our business, financial condition, and results of operations could be negatively impacted.

Technological change may cause our offerings to become obsolete over time. A decrease in our customers' purchases of our offerings could have a material adverse effect on our business, results of operations and financial condition.

The healthcare industry is characterized by rapid technological change. Demand for our services may change in ways that we may not anticipate because of evolving industry standards or as a result of evolving customer needs that are increasingly sophisticated and varied or because of the introduction by competitors of new services and technologies. We may also need to purchase additional equipment, some of which can take several months or more to procure, install and validate, and increase or modify our manufacturing, maintenance, software and computing capabilities to meet changing demand. In addition, we require capital and resources to support the maintenance and improvement of our facilities, including replacing or repairing aging production equipment and updating overall facility master plans. If we are unable to maintain and improve our facilities, we may experience unscheduled equipment downtime and unpredicted machinery failure and become unable to supply our customers with products or services which may affect business continuity. Any such incident or disruption in business continuity could have a material adverse effect on our business, results of operations and financial condition.

We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our manufacturing facilities are located in Gainesville, Georgia, where natural disasters or similar events, like hurricanes, blizzards, tornadoes, fires, floods, earthquakes or explosions or large-scale accidents or power outages, could severely disrupt our operations and have a material adverse effect on our business, prospects, results of operations and financial condition. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our Gainesville facilities, damaged critical infrastructures, such as manufacturing resource planning and enterprise quality systems, or otherwise disrupted operations at that location, it may be difficult or, in certain cases, impossible for us to continue our development, formulation and manufacturing business for a substantial period of time, which could have a material adverse effect on our business, financial condition, and results of operations.

Currently, we maintain insurance coverage against damage to our property and equipment, and to cover business interruption expenses, in an amount we believe is sufficient for our development, formulation and manufacturing operations. However, there can be no assurance that such insurance will continue to be available on acceptable terms or that such insurance will provide adequate protection against actual losses. Even if we maintain adequate insurance coverage, claims could have a material adverse effect on our financial condition, liquidity and results of operations and on our ability to obtain suitable, adequate or cost-effective insurance in the future.

We must comply with environmental and health and safety laws and regulations, which can be expensive and restrict how we do business.

We are subject to federal, state and local laws, rules, regulations and policies concerning the environment and the health and safety of our employees. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could have a material adverse effect on our business, financial condition, and results of operations.

In addition, our business involves the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. As a result, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by those regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources. In addition, although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. If we become subject to any of the foregoing liabilities, our business, financial condition, and results of operations could be materially adversely impacted.

We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business.

We may be subject to litigation or government investigations. These may include claims, lawsuits, and proceedings involving product liability, labor and employment, wage and hour, commercial and other matters. For example, we are subject to securities class action litigation as discussed further in note 9 to our consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K. The outcome of any litigation or government investigation, regardless of its merits, is inherently uncertain. Any lawsuits or government investigations, and the disposition of such lawsuits and government investigations, could be time-consuming and expensive to resolve and divert management attention and resources. Any adverse determination related to litigation or government investigations could adversely affect our operating results, harm our reputation or otherwise negatively impact our business. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter or government investigation could materially affect our future operating results, our cash flows or both.

Our future success depends on our ability to retain our key executives as well as to attract, retain and motivate other qualified personnel.

We are highly dependent on the principal members of our executive team and, in particular, the services of J. David Enloe, Jr., our President and Chief Executive Officer, and Ryan Lake, our Chief Financial Officer, the loss of whose services would adversely impact the achievement of our objectives. We have entered into employment agreements with each of our executive officers. Recruiting and retaining qualified employees for our business, including business development, scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our business development, manufacturing, quality, growth and diversification objectives.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, that could have a material adverse effect on our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including, businesses or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our employees, partners, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, consultants and vendors may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA or DEA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal, state and foreign healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

We face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability.

The use of our products exposes us to the risk of product liability claims as well as potential toxic tort and other types of product liability claims that are inherent in the manufacture of pharmaceutical products. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and negative media attention;
- withdrawal of our customers clinical study participants or adverse effects occurring during such clinical trials;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- decreased demand for our manufacturing services or loss of any of our commercial partners;
- substantial monetary awards to patients or other claimants;
- the inability of our customers to commercialize their product candidates; and
- increased scrutiny and potential investigation by, among others, the FDA, the Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services, State Attorneys General, members of Congress and the public.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

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

As of December 31, 2020, we had federal and state net operating loss carry forwards, or NOLs, of approximately $130.6 million and $127.4 million, respectively. The federal carry forwards for 2008 through 2017 will expire in 2028 through 2037. Federal net operating losses incurred in 2018 and onward have an indefinite expiration under the 2017 Tax Cut & Jobs Act. The state carry forwards including those generated in 2020 will expire in 2028 through 2040. A full allowance for the value of the NOLs is provided for in our consolidated financial statements as of December 31, 2020. We cannot guarantee what the ultimate outcome or amount of the benefit we may receive from the NOLs, if any, will be.

We incur increased costs and demands upon our management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

We are a public company and, as such, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements and liability insurance for our directors and officers. We also incur costs associated with current corporate governance requirements, including certain of the requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as well as rules implemented by the SEC and the Nasdaq Capital Market, the stock exchange on which our common stock is listed. If we fail to comply with current corporate governance requirements, our business may be negatively affected, including by having our common stock delisted from the Nasdaq Capital Market.

The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to continue to significantly impact our legal, insurance and financial compliance costs and to make some activities more time-consuming and costly. We are unable to currently estimate these costs with any degree of certainty. We also expect that these rules and regulations may make it difficult and expensive for us to continue to maintain director and officer liability insurance, and if we are able to maintain such insurance, we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage available to privately-held companies. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors, or the board, or as our executive officers, which could have a material adverse effect on our business.

The security of our information technology systems may be compromised in the event of system failures, unauthorized access, cyberattacks or a deficiency in our cybersecurity, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

We rely extensively on information technology and systems including internet sites, data hosting, physical security, and software applications and platforms. Despite our security measures, our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, power outages, user errors or catastrophic events. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems, by our employees, others with authorized access to our systems or unauthorized persons could negatively impact or interrupt operations. For example, the loss of data from completed or ongoing clinical trials for product candidates could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The use of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our systems or our third-party systems. We could also experience a business interruption, theft of confidential information or reputational damage from malware or other cyberattacks, which may compromise our systems or lead to data leakage, either internally or at our third-party providers.

As part of our business, we maintain large amounts of confidential information, including non-public personal information on our employees. The maintenance of such information is governed by various rules and regulations in the jurisdictions in which we conduct our business, including by the General Data Privacy Regulation, or GDPR, in the European Union. Breaches in security, either internally or at our third-party providers, could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. Although we believe we have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, there can be no assurance that such use or disclosure will not occur.

Any such business interruption, theft of confidential information or reputational damage from malware or other cyberattacks, or violation of personal information laws, could have a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to laws and regulations that address privacy and data security of patients who use our product candidates in the United States and in states in which we conduct our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information. For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

Potential indemnification obligations to Baudax Bio or a refusal of Baudax Bio to indemnify us pursuant to agreements executed in the spin-off could materially adversely affect us.

On November 21, 2019, we distributed all of the then outstanding shares of Baudax Bio common stock to our shareholders in connection with the separation of our Acute Care business. In connection with the distribution, we entered into a separation and distribution agreement and various other agreements (including a transition services agreement, a tax matters agreement, a manufacturing and supply agreement, an employee matters agreement, an intellectual property matters agreement and certain other commercial agreements). These agreements govern the separation and distribution and the relationship between the two companies going forward, including with respect to potential tax-related losses associated with the separation and distribution. They also provide for the performance of services by each company for the benefit of the other for a period of time.

The separation and distribution agreement provides for indemnification obligations designed to make Baudax Bio financially responsible for any liabilities that may exist relating to its business activities, whether incurred prior to or after the distribution, including any pending or future litigation. It is possible that a court would disregard the allocation agreed to between us and Baudax Bio and require us to assume responsibility for obligations allocated to Baudax Bio. Third parties could also seek to hold us responsible for any of these liabilities or obligations, and the indemnity rights we have under the separation and distribution agreement may not be sufficient to fully cover all of these liabilities and obligations. Even if we are successful in obtaining indemnification, we may have to bear costs temporarily. In addition, our indemnity obligations to Baudax Bio may be significant. These risks could negatively affect our business, financial condition or results of operations.

Risks Related to Our Intellectual Property

We own numerous pending patent applications and issued patents in the United States. If our pending patent applications fail to issue or if our issued patents expire or are successfully opposed, invalidated, or rendered unenforceable, our business will be adversely affected.

To protect our proprietary technology, we rely on patents and other intellectual property protections, including trade secrets, nondisclosure agreements and confidentiality provisions.

As of December 31, 2020, we own five issued U.S. patents, numerous foreign patents and have pending applications in the U.S. and several foreign countries relating to Zohydro-ER®, all of which expire on September 12, 2034. We license the Canadian patent application relating to this technology to our commercial partner, Paladin Labs Inc., in Canada. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or foreign countries. Even if the patents do successfully issue, third parties may challenge the patents or the inventorship thereof, which can lead to an issued patent being found invalid, unenforceable or can otherwise alter the ownership of the patents.

The issuance of any patent is not a certainty. Unless and until our pending applications issue, their protective scope is impossible to determine It is impossible to predict whether or how many of these applications will result in issued patents and patents that issue may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of patent exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which may limit our ability to prevent others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, upon expiration of a patent, we may be limited in our ability to prevent others from using or commercializing subject matter covered by the expired patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The Leahy Smith America Invents Act, or the Leahy Smith Act, enacted in September 2011, brought significant changes to the U.S. patent system. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office continues to develop and implement new regulations and procedures to govern administration of the Leahy Smith Act, and many of the substantive changes to patent law associated with the Leahy Smith Act became effective on March 16, 2013. The Leahy Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patent, all of which could have a material adverse effect on our business and financial condition.

Litigation involving patents, patent applications and other proprietary rights is expensive and time-consuming. If we are involved in such litigation, it could interfere with our business.

Our success depends in part on not infringing patents and proprietary rights of third parties. Although we are not currently aware of litigation or other proceedings or third-party claims of intellectual property infringement related to our technologies or business activities, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights.

In a patent infringement claim against us, we may assert, as a defense, that we do not infringe the relevant patent claims, that the patent is invalid or both. The strength of our defenses will depend on the patents asserted, the interpretation of these patents and/or our ability to invalidate the asserted patents. However, we could be unsuccessful in advancing non-infringement and/or invalidity arguments in our defense. In the United States, issued patents enjoy a presumption of validity, and the party challenging the validity of a patent claim must present clear and convincing evidence of invalidity, which is a high burden of proof. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a low burden of proof.

If we were found by a court to have infringed a valid patent claim, we could be prevented from using the patented technology or be required to pay the owner of the patent for the right to license the patented technology. If we decide to pursue a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

In addition, because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive, particularly as a public company, communications from competitors and other companies alleging that we may be infringing their patents, trade secrets or other intellectual property rights, offering licenses to such intellectual property or threatening litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other proprietary rights against us. We may need to expend considerable resources to counter such claims and may not be able to be successful in our defense. Our business may suffer if a finding of infringement is established.

Generic competitors can challenge the U.S. patents protecting our commercial partners' product candidates by filing an ANDA or an NDA for a generic or a modified version of our commercial partners' product candidates.

Separate and apart from the protection provided under the U.S. patent laws, drug candidates may be subject to the provisions of the Hatch- Waxman Act, which may provide drug candidates with either a three- or five-year period of marketing exclusivity following receipt of FDA approval. The Hatch-Waxman Act prohibits the FDA from accepting the filing of an ANDA application (for a generic product) or a 505(b)(2) NDA (for a modified version of the product) for three years for active drug ingredients previously approved by the FDA or for five years for active drug ingredients not previously approved by the FDA.

There is an exception, however, for newly approved molecules that allows competitors to challenge a patent beginning four years into the five-year exclusivity period by alleging that one or more of the patents listed in the FDA's list of approved drug products are invalid, unenforceable and/or not infringed and submitting an ANDA for a generic version of a drug candidate. This patent challenge is commonly known as a Paragraph IV certification. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time.

If a generic company is able to successfully challenge the patents covering drug candidates by obtaining FDA approval for an ANDA, the generic company may choose to launch a generic version of a drug candidate. Any launch of a generic version of our drug candidates prior to the expiration of patent protection will have a material adverse effect on our revenues and our results of operations.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged in the United States to date. The pharmaceutical patent situation outside of the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patent license we obtain is deemed invalid and/or unenforceable, it could impact our ability to commercialize or partner our technology.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- an individual or party will not challenge inventorship, that if successful, could have an adverse effect on our business;
- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; or
- the patents of others will not have an adverse effect on our business.

If we do not adequately protect our proprietary rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may possess, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our product candidates and delay or render impossible our achievement of profitability.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We may rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects on our competitive business position.

Our ability to manufacture products for our commercial partners may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture products for our commercial partners, to utilize third parties to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents and other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacturing and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of the products to which those intellectual property rights apply, which could materially harm our business, operating results and financial condition.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications.

We have systems in place to remind us to pay periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees, and we employ an outside law firm to pay these fees. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ an outside law firm and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors may be able to enter the market, which would have a material adverse effect on our business.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. If we are unable to adequately enforce our intellectual property rights throughout the world, our business, financial condition, and results of operations could be adversely impacted.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our products that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Risks Relating to Our Securities

The market price and trading volume of our common stock have been and may continue to be volatile, which could result in rapid and substantial losses for our shareholders.

The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future. An active, liquid and orderly market for our common stock may not be sustained, which could depress the trading price of our common stock or cause it to continue to be highly volatile or subject to wide fluctuations. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include, among other things:

- FDA, state or international regulatory actions, including actions on regulatory applications for any of our commercial partners' product candidates;
- legislative or regulatory changes;
- judicial pronouncements interpreting laws and regulations;
- changes in government programs;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- changes in demand for or pricing of our customers' products;
- the sales ramp and trajectory for our formulation, development and manufacturing services;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- changes in accounting principles;
- litigation or public concern about the safety of our products or similar products;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;
- our announcement of financing transactions, including debt, convertible notes, etc.; and
- actions by institutional or activist shareholders.

These broad market and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and decreases in the market price of a company's securities, securities class action litigation has often been instituted against these companies. Following the decrease in our trading price in May 2018, a securities class action lawsuit was filed against us and certain of our officers and directors for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. On December 10, 2018, lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers and directors as defendants. On February 8, 2019, we filed a motion to dismiss the amended complaint in its entirety which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, we filed our response and briefing was completed on the motion to dismiss. In response to questions from the Judge, the parties submitted supplemental briefs with regard to the motion to dismiss the amended complaint during the fall of 2019. On February 18, 2020, the motion to dismiss was granted without prejudice. On April 25, 2020, the plaintiff filed a second amended complaint. We filed a motion to dismiss the second amended complaint on June 18, 2020. The plaintiff filed an opposition to our motion to dismiss on August 17, 2020 and on September 16, 2020, we filed a reply in support of our motion to dismiss. In connection with the separation from Baudax Bio, Baudax Bio accepted assignment from us of all of our obligations in connection with the litigation and agreed to indemnify us for all liabilities related to the litigation. This litigation, and any other securities class actions that may be brought against us, could result in substantial costs and a diversion of our management's attention and resources.

We have never paid cash dividends on our common stock and do not intend to do so for the foreseeable future.

We have never paid cash dividends on our common stock and we do not anticipate that we will pay any cash dividends on our common stock for the foreseeable future. Accordingly, any return on an investment in our common stock will be realized, if at all, only when shareholders sell their shares. In addition, our failure to pay cash dividends may make our stock less attractive to investors, adversely impacting trading volume and price.

The concentration of our capital stock ownership with our directors and their affiliated entities and our executive officers will limit shareholders' abilities to influence certain corporate matters.

Our directors and their affiliated entities, and our executive officers, beneficially own, in the aggregate, approximately 12% of our outstanding common stock as of December 31, 2020. As a result, these shareholders are collectively able to influence matters requiring approval of our shareholders, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of all or substantially all of our assets. Such influence may delay, prevent or deter a change in control of our company, even when such a change may be in the best interests of some shareholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our shareholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might adversely affect the prevailing market price of our common stock.

Some provisions of our charter documents and Pennsylvania law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders, and may prevent attempts by our shareholders to replace or remove our current management.

Provisions in our articles of incorporation and amended and restated bylaws could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our shareholders, or remove our current management. These include provisions that:

- divide our board of directors into three classes with staggered three-year terms;
- provide that a special meeting of shareholders may be called only by a majority of our board of directors;
- establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of director;
- provide that shareholders may only act at a duly organized meeting; and
- provide that members of our board of directors may be removed from office by our shareholders only for cause by the affirmative vote of 75% of the total voting power of all shares entitled to vote generally in the election of directors.

These provisions may frustrate or prevent any attempts by ourshareholders to replace or remove our current management by making it more difficult forshareholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Pennsylvania, we are governed by the provisions of the Pennsylvania Business Corporation Law of 1988, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our shareholders. Under Pennsylvania law, a corporation may not, in general, engage in a business combination with any holder of 20% or more of its capital stock unless the holder has held the stock for five years or, among other things, the board of directors has approved the transaction. Any provision of our articles of incorporation or bylaws or Pennsylvania law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

General Risk Factors

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of shares by these shareholders could have a material adverse effect on the trading price of our common stock.

If securities or industry analysts do not continue to publish research or reports, or if they publish unfavorable research or reports, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We currently have limited research coverage by securities and industry analysts. If additional securities or industry analysts do not commence coverage of our company, the trading price for our stock could be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be frequently evaluated. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors (the latter requirement does not apply to smaller reporting companies-we qualify as a smaller reporting company). Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355. We currently operate our owned 97,000 square foot, DEA-licensed facility in Gainesville, Georgia and leased 24,000 square foot development and high-potency product services facility, also in Gainesville, GA, which expires on June 30, 2025.

Item 3. Legal Proceedings

Information regarding legal and regulatory proceedings is set forth in note 9 to our consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K, and is incorporated by reference herein. We are also engaged in numerous other legal actions arising in the ordinary course of our business (such as, for example, proceedings relating to employment matters or the initiation or defense of proceedings relating to intellectual property rights) and, while there can be no assurance, we believe that the ultimate outcome of these other legal actions will not have a material adverse effect on our business, results of operations, financial condition or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "REPH."

Holders of Common Stock

As of February 19, 2021, there were eight holders of record of our common stock. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and our ability to pay cash dividends is currently prohibited by the terms of our credit facility with Athyrium. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs and plans for expansion.

Issuer Repurchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

Other information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Performance Graph

Not applicable.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions and other factors that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. Our actual results may differ materially from those discussed below. Please see "Forward-Looking Statements" and "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K for factors that could cause or contribute to such differences.

Overview

We are a dedicated contract development and manufacturing organization, or CDMO, solving complex formulation and manufacturing challenges for companies developing oral solid dose drug products. We leverage our formulation and development expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies and know-how for partners who develop and commercialize or plan to commercialize these products. In 2020, we launched our clinical trials support services capabilities, which includes preparation of clinical trial supplies, as well as specialized services dedicated to the development and Good Manufacturing Practices, or GMP, of high-potency products. We operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia, as well as a 24,000 square foot development, high-potency product and clinical packaging facility in Gainesville, Georgia that we opened in October 2018. We currently develop and/or manufacture the following key products with our key commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM and Verapamil SR, as well as supporting development stage products.

Our manufacturing and development capabilities include formulation, product development from formulation through clinical trial and commercial manufacturing, and specialized capabilities for solid oral dosage forms, extended release and controlled substance manufacturing, as well as high potency development and manufacturing. In a typical collaboration, we work with our partners to develop product candidates, or new formulations of existing product candidates, and may license certain intellectual property to such partners. We also typically exclusively manufacture and supply clinical and commercial supplies of these proprietary products and product candidates.

We have used cash flow generated by our business primarily to fund the growth of our CDMO business, fund our historical Acute Care business, which was spun off in November 2019, and to make payments under our credit facility. We believe our business will continue to contribute cash to fund our growth, make payments under our credit facility and other general corporate purposes.

Our consolidated results of operations and financial position included in this Annual Report on Form 10-K reflect the financial results of Baudax Bio as a discontinued operation for all periods presented. For additional information on the spin-off of Baudax Bio please read note 3 to our consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K.

COVID-19

We continue to closely monitor developments related to the COVID-19 pandemic, which continues to have adverse effects on the U.S. and world economies, including the commercial activities of our customers and their peers. While we are committed to continue providing essential pharmaceutical products to our customers, we are also taking all necessary measures to protect the health and safety of our employees. These developments include:

Operations. We have instituted protocols to have appropriate personnel work remotely and have implemented strict social distancing and other protective measures for those employees continuing to support essential operations at our work locations in order to ensure the health of our employees while continuing to provide critical products. Our sales, manufacturing and development efforts have continued since the outbreak of the pandemic. Our cost of sales has increased as a percentage of revenues in part due to lower commercial manufacturing volumes, and the related impact on fixed costs expensed through cost of sales, despite making reductions in the work force and implementing cost saving measures. There are also some incremental expenses associated with safe practices for our organization due to COVID-19.

Business Development. We have experienced lower than expected new development business growth, which we believe is primarily attributable to COVID-19. Concerns surrounding COVID-19 have resulted in our adoption of new methods for meeting and contacting customers, have slowed customer access, and have caused delays in plans for development services by some customers and prospects for a variety of reasons, such as concerns about the timing of clinical trials.

Manufacturing Demand. We believe that there has been lower end-user demand for some of the commercial products we manufacture for our customers due to the effects of COVID-19. Third party national data demonstrates that there has been a meaningful impact of COVID-19 on the reduction of total prescriptions filled by patients across most therapeutic areas, including chronic cardiovascular and pediatric medications.

Our sales and manufacturing operations have been disrupted as a result of the pandemic because of production slowdowns, stoppages, or decreased demand for the products we manufacture, and we expect such disruptions to continue through at least the first half of 2021. Given the uncertain scope and duration of the pandemic, the extent to which the pandemic will continue to impact our financial results remains uncertain in terms of manufacturing volumes and certain profit sharing results, even when our partners have not experienced loss of market share, in part due to reduced total prescription (TRx) rates for many chronic therapeutics. However, we will continue to monitor the situation closely, we have taken steps to reduce costs and drive more new business, and we are actively evaluating various ways to further conserve operational resources.

Financial Overview

Recent Developments

Some recent developments have occurred that have impacted and are expected to continue to impact full year expected results, including:

- Third party data has shown a decrease in prescriptions filled during COVID-19 during 2020 for a number of the commercial products we manufacture for our customers. We continue to see the COVID-19 pandemic resulting in lower end-user demand for our manufacturing services and inventory rebalancing by our commercial partners with respect to these products, especially since the duration of the COVID-19 pandemic and its impacts are not predictable at this time.

- With regard to the previously reported return to the market of a competitor to one of our key customers for certain product strengths that had previously been out of the market, this product has recovered to an observed percentage of approximately 50% market share. While total unit volumes have declined during COVID-19, relative market share has remained steady for both parties. This has negatively impacted both anticipated manufacturing volumes and profit sharing for this key customer.

- We received notification reported in the first quarter of 2020 from two of our customers of discontinuations for two commercial product lines. These discontinuances decreased revenues by approximately $5.7 million for 2020 compared to 2019, and we anticipate decreases in revenue of approximately $5 to $7 million for 2021 compared to 2020 related to these product discontinuances.

- We have experienced slower than expected new project starts, which we believe is primarily attributable to the COVID-19 pandemic. Concerns surrounding COVID-19 have resulted in delays in plans for development services by some customers and prospects for a variety of reasons, such as concerns about timing of clinical trials, etc.

As a result of these recent events, we implemented operating improvement initiatives including two separate reduction in force actions during the first half of 2020 as well as other initiatives. We estimate that these initiatives will provide an annual savings of approximately $3.4 million in fiscal year 2021. Additional cost saving measures continue to be assessed.

Revenues

During the years ended December 31, 2020, 2019 and 2018, we recognized revenues from three revenue streams: manufacturing revenue, profit-sharing revenue and research and development revenue.

Manufacturing revenue

We recognize manufacturing revenue from the sale of products we manufacture for our commercial partners. Manufacturing revenues are recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration we expect to be entitled to as specified in the agreement with the commercial partner, which could include pricing and volume-based adjustments.

Profit-sharing revenue

We recognize profit-sharing or royalty revenue, collectively referred to as profit-sharing revenue, related to the sale of products by our commercial partners that incorporate our technologies. Profit-sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based profit-sharing and the license is deemed to be the predominant item to which the profit-sharing relates, we recognize revenue when the related sales occur by the commercial partner. For arrangements that include sales-based profit-sharing and the license is not deemed to be the predominant item to which the profit-sharing relates, we recognize revenue when the performance obligation to which the profit-sharing has been allocated has been satisfied, which is upon transfer of control of a product to a customer. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions. Estimated variable consideration is partially constrained due to the uncertainty of price adjustments made by our commercial partners, which are outside of our control. Factors causing price adjustments by our commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing.

Research and development revenue

Research and development revenue includes services associated with formulation, process development, clinical trial material and clinical trial support services, as well as custom development of manufacturing processes and analytical methods for a customer's non-clinical, clinical and commercial products. Such revenues are recognized at a point in time or over time depending on the nature and particular facts and circumstances associated with the contract terms.

In contracts that specify milestones, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which we have continuing performance obligations are deferred and recognized over the period of performance. Milestone payments that are not within our control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

In contracts that require revenue recognition over time, we utilize input or output methods, depending on the specifics of the contract, that compare the cumulative work-in-process to date to the most current estimates for the entire performance obligation. Under these contracts, the customer typically owns the product details and process, which have no alternative use. These projects are customized to each customer to meet its specifications and typically only one performance obligation is included. Each project represents a distinct service that is sold separately and has stand-alone value to the customer. The customer also retains control of its product as the product is being created or enhanced by our services and can make changes to its process or specifications upon request.

Research and development expenses

Research and development expenses consist of costs incurred for our product and formulation development activities, including regulatory support. We expense research and development costs as incurred. Advanced payments for good and services that will be used in future research and development activities are initially recorded as prepaid expenses and expensed as the activity is performed or when the goods have been received. In 2018, these costs included salaries and related costs for personnel in research and development and regulatory functions. In the fourth quarter of 2018, we shifted the focus of these personnel to revenue-generating activities and, as such, these costs are included as a cost of sales beginning in the fourth quarter of 2018.

Selling, general and administrative expenses

Selling, general and administrative expenses consists of salaries and related costs for corporate administrative, public company costs, business development personnel as well as legal, patent-related expenses and consulting fees. Public company costs include compliance, auditing services, tax services, insurance and investor relations. A significant portion of these public company costs related to a more complex organization with multiple segments in 2018 and 2019. These costs were lower in 2020 and are expected to remain lower in future periods, excluding non-cash expenses and new initiatives.

We expect our business development expenses to increase in 2021 as we continue to expand our sales team in various geographies, in anticipation of business growth from new formulation and development capabilities.

Amortization of intangible assets

We recognize amortization expense related to the intangible asset for our contract manufacturing relationships on a straight-line basis over an estimated useful life of six years.

Change in fair value of warrants

We have classified as liabilities certain warrants that contained a contingent net cash settlement feature upon a change in control. The fair value of these warrants was remeasured through settlement or expiration with changes in fair value recognized within the consolidated statements of operations. All remaining liability classified warrants were exercised in November 2019. A fair value determination at the time of the exercise occurred and is included in the change in warrant valuation for the year ended December 31, 2019.

Interest expense

Interest expense for the periods presented primarily relates to our Athyrium senior secured term loans, the amortization of related financing costs and interest expense on a promissory note with PNC Bank under the Paycheck Protection Program, or PPP, of the Coronavirus Aid, Relief and Economic Security Act of 2020, collectively the PPP Loan.

Net operating losses and tax carryforwards

As of December 31, 2020, we had federal and state net operating loss carry forwards of approximately $130.6 million and $127.4 million, respectively. We also had federal and state research and development tax credit carryforwards of $4.4 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. With the exception of the 2020, 2019, and 2018 federal net operating losses, which have an indefinite carry forward period, these federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. We believe that it is more likely than not that the deferred income tax assets associated with our U.S. operations will not be realized, and as such, there is a full valuation allowance against our U.S. deferred tax assets.

Results of Operations

Comparison of the years ended December 31, 2020 and 2019

	Year ended December 31,	
(in millions)	**2020**	**2019**
Revenue	$ 66.5	$ 99.2
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	54.1	51.0
Selling, general and administrative	18.1	19.9
Amortization of intangible assets	2.6	2.6
Change in warrant valuation	—	2.1
Total operating expenses	74.8	75.6
Operating (loss) income from continuing operations	(8.3)	23.6
Interest expense	(19.2)	(19.0)
(Loss) income from continuing operations before income taxes	(27.5)	4.6
Loss on discontinued operations	—	(23.2)
Net loss	$ (27.5)	$ (18.6)

Revenue. The decrease of $32.7 million was primarily the result of customer ordering patterns in the prior year and the loss of Verapamil SR market share by a commercial partner in the first quarter of 2020 due to the re-entry of a competitor. Our commercial partner has sustained its market position for Verapamil SR capsules since the end of the first quarter of 2020. The COVID-19 pandemic has resulted in decreased end-user demand, inventory rebalancing by our commercial partners and slower than expected new business starts. In addition, revenue declined due to the discontinuation of two commercial product lines by our commercial partners. Higher revenues from our clinical trial materials new business growth activities has partially offset the decrease, including a significant new commercial product tech transfer project.

Cost of sales. The increase of $3.1 million was not proportionate to the decrease in revenue primarily due to lower commercial manufacturing volumes and the related impact on fixed costs expensed through cost of sales, despite making reductions in the work force and implementing cost saving measures. Cost savings generated from these activities are expected to continue into 2021. Further contributing to cost of sales was increased cost of development sales on higher clinical trial material new business revenues.

Selling, general and administrative. The decrease of $1.8 million was primarily related to lower public company costs, which were partially offset by our new business efforts and the addition of the clinical trial support services to our early GMP offering in the second quarter of 2020.

Amortization of intangible assets. Amortization expense was $2.6 million for both periods, which was related to the amortization of the CDMO royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Change in warrant valuation. Previously, certain warrants were outstanding whose fair value was remeasured each period with changes in fair value recognized in earnings. The last of those warrants were exercised in November 2019.

Interest expense. The increase of $0.2 million was primarily due to additional term loan borrowings under the Credit Agreement with Athyrium in the first quarter of 2019 offset by a decrease in the LIBOR base rate of interest on our term loans under the Credit Agreement.

Discontinued operations. In November 2019, our former Acute Care business was spun-out from us through our former wholly-owned subsidiary, Baudax Bio. As a result, that business's results are included in the 2019 period but not the 2020 period.

Comparison of the years ended December 31, 2019 and 2018

	Year ended December 31,	
	2019	**2018**
	(amounts in thousands)	
Revenue	$ 99.2	$ 77.3
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	51.0	43.2
Research and development	—	4.4
Selling, general and administrative	19.9	14.3
Amortization of intangible assets	2.6	2.6
Change in warrant valuation	2.1	0.3
Total operating expenses	75.6	64.8
Operating income from continuing operations	23.6	12.5
Interest expense	(19.0)	(8.1)
Income from continuing operations before income taxes	4.6	4.4
Income tax expense	—	(17.5)
Net income (loss) from continuing operations	4.6	(13.1)
Loss on discontinued operations	(23.2)	(66.6)
Net loss	$ (18.6)	$ (79.7)

Revenue. The increase of $21.9 million was primarily due to increased profit-sharing royalties recognized from one of our commercial partners and an increase in product sales to various commercial partners.

Cost of sales. The increase of $7.8 million was primarily due to product mix and expanded service and development capabilities as well as growth in manufacturing demand.

Research and development. There were no research and development expenses in 2019. Our research and development expenses were $4.4 million in 2018. In the fourth quarter of 2018, we shifted the focus of our development activities to support revenue generating activities and therefore such costs are now included in cost of sales above.

Selling, general and administrative. The increase of $5.6 million was primarily due to higher public company costs (including corporate initiatives), which increased by $4.1 million to $16.3 million in 2019 compared to $12.2 million in 2018. The remaining $1.5 million increase was driven by higher business development costs, as we expanded our sales team in various geographies in anticipation of business growth from new formulation and development capabilities.

Amortization of intangible assets. Amortization expense was $2.6 million for both periods, which was related to the amortization of the CDMO royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest expense. The increase in interest expense was due to a higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs.

Income tax expense. As a result of recording a full valuation allowance, there was no income tax provision or benefit for 2019. For 2018, the income tax expense reflects the recording of a full valuation allowance in the fourth quarter of 2018. As discussed in note 15 to the consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K, we believe that it is more likely than not that the deferred income tax assets associated with our U.S. operations will not be realized, and as such, there is a full valuation allowance against our U.S. deferred tax assets.

Liquidity and Capital Resources

At December 31, 2020, we had $23.8 million in cash and cash equivalents.

Since our inception, we have financed our operations and capital expenditures primarily from the issuance of equity and debt. During 2020, our capital expenditures were $7.6 million to scale and support our expansion of capabilities.

We are party to a credit agreement with Athyrium, or the Credit Agreement, which has been fully drawn. The Credit Agreement was recently amended on February 19, 2021 and currently requires us to repay the outstanding principal amount of $100.0 million on March 31, 2023. The amendment also changes certain other terms and covenants that allow the Company to pursue additional acquisitions and ease certain requirements surrounding the financial covenants. Additional details about the Credit Agreement and the recent amendment are provided in notes 10 and 18 to the consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K.

We are party to a $3.3 million PPP Note which has a two-year term and matures on May 12, 2022. On October 6, 2020, we applied for forgiveness of the PPP Note and expect the full balance of the note to be forgiven during the first half of 2021, which would result in a $3.3 million gain on extinguishment of debt being recognized in earnings. However, no assurance can be given that the balance of the PPP Note will be forgiven, in part or in whole. Additional details are provided in note 10 to the consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K.

We are also party to an amended common stock purchase agreement with Aspire Capital Fund LLC, or Aspire Capital. The amended agreement provided that, upon the terms and subject to the conditions and limitations set forth in the agreement, Aspire Capital was committed to purchase, at the Company's sole election, up to an aggregate of $30.0 million or 4.7 million of additional shares of common stock. As of December 31, 2020, all available shares have been sold under the agreement. See note 11 to the consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K for additional information.

We may require additional financing and if we do, we may raise such additional funds through debt refinancing, bank or other loans, through strategic development, licensing activities, sale of assets and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Further, our ability to access capital market or otherwise raise capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. Additional debt or equity financing, if available, may be dilutive to the holders of our common stock and may involve significant cash payment obligations and covenants that restrict our ability to operate our business or access to capital.

Sources and Uses of Cash

	Year ended December 31,		
(amounts in millions)	**2020**	**2019**	**2018**
Net cash provided by (used in) continuing operations:			
Operating activities	$ 9.2	$ 16.2	$ 11.0
Investing activities	(7.6)	(8.3)	(3.7)
Financing activities	4.1	26.0	27.7
Net cash provided by continuing operations	$ 5.7	$ 33.9	$ 35.0
Net cash used in discontinued operations	$ (1.2)	$ (53.2)	$ (57.5)

Continuing operations

Cash flows from operating activities during all three years represents our income or loss from continuing operations as adjusted for stock-based compensation, depreciation, non-cash interest expense, changes in fair value of warrants and amortization of intangibles, as well as changes in operating assets and liabilities. The decrease in cash flows from operations was primarily due to the increase in our net loss from continuing operations, partially offset by cash provided by decreases in accounts receivable, our contract assets and inventory due to lower revenue levels.

Net cash used in investing activities for each of the three years primarily relates to capital expenditures to scale and support our expansion of capabilities. Net cash used in investing activities for 2019 and 2018 also included offsetting purchases and maturities of short-term investments.

Net cash provided by financing activities included:

- During 2020, net proceeds of $11.1 million from issuance of common stock through our common stock purchase agreement with Aspire Capital and $4.4 million from a PPP Note, offset by a $1.1 million repayment of the PPP Note, partially offset by $10.1 million to repay term loans with Athyrium and $1.1 million to pay employee tax withholdings upon vesting of equity awards.

- During 2019, net proceeds of $43.6 million from issuance of term loans with Athyrium and $6.0 million from the exercise of options, partially offset by the contribution of $19.0 million to Baudax Bio in connection with the Separation, payment of $2.9 million of financing costs related to the issuance of term loans with Athyrium and $1.7 million to pay employee tax withholdings upon vesting of equity awards.

- During 2018, proceeds of $10.0 million from issuance of terms loans with Athyrium, $17.0 million from issuance of common stock through our common stock purchase agreement with Aspire Capital and $1.8 million from the exercise of options, partially offset by $1.0 million to pay financing costs related to the issuance of term loans with Athyrium.

Discontinued operations

Net cash used in discontinued operations during 2020 was used to settle outstanding liabilities related to our Acute Care business and for 2019 and 2018 was used primarily to fund the research activities of our former Acute Care business.

Forward-looking factors

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the extent to which we in-license, acquire or invest in products, businesses and technologies;

- the timing and extent of our manufacturing and capital expenditures;

- our ability to maintain or expand our relationships and contracts with our commercial partners;

- our ability to grow and diversify our business with new customers, including our ability to meet desired project outcomes with development customers;

- our ability to regain profitability;

- our ability to comply with stringent U.S. & foreign government regulation in the manufacture of pharmaceutical products, including cGMP and U.S. DEA requirements;

- our ability to raise additional funds through equity or debt financings or sale of certain assets;

- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and

- the extent to which health epidemics and other outbreaks of communicable diseases, including the ongoing COVID-19 pandemic, could disrupt our operations or materially and adversely affect our business and financial conditions.

We might use existing cash and cash equivalents on hand, additional debt, equity financing, sale of assets or out-licensing revenue or a combination thereof to fund our operations or acquisitions. If we increase our debt levels, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. Our shareholders may experience dilution as a result of the issuance of additional equity or debt securities. This dilution may be significant depending upon the amount of equity or debt securities that we issue and the prices at which we issue any securities.

Contractual Commitments

The table below reflects our contractual commitments as of December 31, 2020:

	Payments due by period				
(in millions)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Debt obligations (1):					
Principal	$ 120.5	$ 1.5	$ 119.0	$ —	$ —
Interest	27.3	12.6	14.7	—	—
Purchase obligations (2)	3.6	3.6	—	—	—
Operating leases (3)	0.7	0.2	0.3	0.2	—
Other long-term liabilities (4)	1.3	1.0	0.3		
Total	$ 153.4	$ 18.9	$ 134.3	$ 0.2	$ —

(1) Debt obligations consist of principal, an exit fee of 1% of that principal, and interest on $116.0 million of outstanding term loans under our credit facility with Athyrium in addition to principal and interest on $3.3 million of outstanding borrowings under the PPP Note. Because the Athyrium term loans bear interest at a variable rate based on LIBOR, we estimated future interest commitments utilizing the LIBOR rate as of December 31, 2020. In accordance with U.S. GAAP, the future interest obligations are not recorded on our consolidated balance sheet.

(2) Purchase obligations consist of cancelable and non-cancelable purchase commitments related to inventory, capital expenditures and other goods or services. In accordance with U.S. GAAP, these obligations are not recorded on our consolidated balance sheets.

(3) We are party to a seven-year operating lease for a development facility in Georgia that ends in 2025. See note 16 to the consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K.

(4) We have entered into employment agreements with certain of our named executive officers. In accordance with U.S. GAAP, these potential obligations are not recorded on our consolidated balance sheet. See note 9 to the consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. 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 the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We have determined that certain accounting policies and estimates are critical to the preparation of the financial statements. We have prepared the following additional disclosures to supplement our summary of significant accounting policies located in note 2 to the consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K.

Revenue recognition for variable consideration in sales-based profit-sharing arrangements

For sales-based profit-sharing where the license for intellectual property is not deemed to be the predominant item to which the profit-sharing relates, we recognize revenue upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions.

We are required to exercise significant judgment to estimate the value of the variable consideration, which we partially constrain due to the uncertainty of price adjustments made by our commercial partners, which are outside of our control. Factors causing price adjustments by our commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing. If we were to increase or decrease the percentage value of the constraint by 5%, we would recognize a corresponding decrease or increase, respectively, to revenue and earnings of $0.5 million.

Impairment of goodwill

We are required to review, on an annual basis, the carrying value of goodwill to determine whether impairment may exist. The impairment analysis for goodwill consists of an optional qualitative assessment potentially followed by a quantitative analysis. If we determine that the carrying value of our reporting unit exceeds its fair value, an impairment charge to goodwill is recorded for the excess.

The critical judgments involved in our annual qualitative test include an assessment of unfavorable events and a judgment whether those events put our goodwill at risk of impairment, which if determined to be at risk would require us to perform a quantitative test. The critical judgments and estimates in our quantitative test include selection and weighting of available valuation methods and the selection of assumptions that may be used in those methods.

In 2020, we concluded qualitatively that our goodwill was not at risk of impairment due to the substantial excess of fair value over the carrying value of our reporting unit that we observed in prior period quantitative testing. The carrying value of our goodwill was $4.3 million at December 31, 2020. Any changes to our judgments or estimates could result in a goodwill impairment of up to that amount in a future period.

Impairment of long-lived assets

We are required to review the carrying value of long-lived assets, such as property, plant and equipment or amortizable intangible assets, for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of individual assets or asset groups may not be recoverable.

Assumptions and estimates used in the evaluation of impairment are subjective, and changes in these assumptions may negatively impact projected undiscounted cash flows, which could result in impairment charges in future periods. On an ongoing periodic basis, we evaluate our long-lived assets for indicators of impairment such as economic, governmental or regulatory events.

In 2020, we received notification from a commercial partner of a discontinuation of a commercial product line. As a result of this event, we recognized $966 of impairment expense related to property, plant and equipment associated with that product line.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. At December 31, 2020, we had approximately $6.6 million invested in money market instruments. We believe our policy of investing in highly-rated securities, whose liquidities are, at December 31, 2020, all less than two months, minimizes such risks. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio. We do not enter into investments for trading or speculative purposes. Our Athyrium secured term loan interest expense is based on the current committed rate of three-month LIBOR plus 9.75% with a 1.0% LIBOR floor. A fluctuation in LIBOR of 0.25% would result in a charge of $0.3 million of interest expense over a twelve-month period.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements and the report of our independent registered public accounting firm are included at the end of this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2020. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual 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 a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the 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 and procedures included in such controls may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management's processes and assessment, as described above, management has concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information with respect to this item will be set forth in the Proxy Statement for the 2021 Annual Meeting of Shareholders, or the Proxy Statement, under the headings "Board of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Corporate Governance and Risk Management" and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 11. Executive Compensation

Information with respect to this item will be set forth in the Proxy Statement under the headings "Director Compensation," "Executive Compensation," and "Corporate Governance and Risk Management" is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters

Information with respect to this item will be set forth in the Proxy Statement under the headings "Security Ownership of Directors, Certain Beneficial Owners and Management," "Executive Compensation," and "Director Compensation," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information with respect to this item will be set forth in the Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Corporate Governance and Risk Management" and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 14. Principal Accounting Fees and Services

Information with respect to this item will be set forth in the Proxy Statement under the heading "Independent Registered Public Accounting Firm," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

PART IV

Item 15. Exhibits, Consolidated Financial Statement Schedules

(a)(1) Consolidated Financial Statements.

The following consolidated financial statements are filed as a part of this Annual Report on Form 10-K:

- Consolidated Balance Sheets as of December 31, 2020 and 2019
- Consolidated Statements of Operations for the three years in the period ended December 31, 2020
- Consolidated Statements of Shareholders' Equity or Deficit for the three years in the period ended December 31, 2020
- Consolidated Statements of Cash Flows for the three years in the period ended December 31, 2020

(a)(2) Consolidated Financial Statement Schedules.

Not applicable.

(a)(3); (b) Exhibits:

Exhibit No.	Description	Method of Filing
2.1	Separation Agreement dated as of November 20, 2019 by and between Recro Pharma, Inc. and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-36329).
3.1	Second Amended and Restated Articles of Incorporation of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
3.2	Third Amended and Restated Bylaws of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
4.1†	Common Stock Purchase Warrant, dated November 17, 2017, in favor of Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
4.2†	Common Stock Purchase Warrant, dated November 17, 2017, in favor of Athyrium Opportunities II Acquisition LP.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
4.3	Description of Securities	Incorporated herein by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-K filed on March 4, 2020 (File No. 001-36329).
10.1†	Tax Matters Agreement, dated as of November 20, 2019, by and between Recro Pharma, Inc. and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-36329).
10.2†	Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.3	Supplemental Agreement, dated December 8, 2004, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).

Exhibit No.	Description	Method of Filing
10.4	Supplemental Agreement No. 2, dated January 17, 2014, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.5†	Supplemental Agreement No. 3, dated April 15, 2019, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2019 (File No. 001-36329).
10.6•	Asset Transfer and License Agreement, dated April 10, 2015, between Alkermes Pharma Ireland Limited and DV Technology, Inc.	Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015 (File No. 001-36329).
10.7•	Amendment to Asset Transfer and License Agreement, dated December 23, 2015, between Alkermes Pharma Ireland Limited and Recro Gainesville LLC.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 23, 2015 (File No. 001-36329).
10.8•	Second Amendment to Asset Transfer and License Agreement, dated December 20, 2018, between Alkermes Pharma Ireland Limited and Recro Gainesville LLC.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 28, 2018 (File No. 001-36329).
10.9†	Manufacturing and Supply Agreement, dated as of February 8, 2019, by and between Recro Gainesville LLC and Novartis Pharma AG.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed on March 6, 2019 (File No. 001-3632).
10.10	License and Supply Agreement, dated as of January 1, 2014, by and between Alkermes Pharma Ireland Limited and Kremers Urban Pharmaceuticals, Inc.	Incorporated herein by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K filed on March 4, 2020 (File No. 001-36329).
10.11	Amendment No. 1 to License and Supply Agreement, dated as of September 6, 2018, by and between Recro Gainesville LLC and Kremers Urban Pharmaceuticals, Inc.	Incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K filed on March 4, 2020 (File No. 001-36329).
10.12	Amendment No. 2 to License and Supply Agreement, dated as of November 5, 2020 by and among Recro Gainesville LLC, Kremers Urban Pharmaceuticals, Inc. and Lannett Company, Inc.	Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 10, 2020 (File No. 001-36329).
10.13†	Credit Agreement, dated as of November 17, 2017, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP. *	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
10.14	Security Agreement, dated as of November 17, 2017, by Recro Pharma, Inc. in favor of Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
10.15	First Amendment to Credit Agreement and Investment Documents, dated as of December 28, 2018, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 4, 2019 (File No. 001-36329).

Exhibit No.	Description	Method of Filing
10.16	Second Amendment to Credit Agreement and Investment Documents, dated as of February 28, 2019, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 4, 2019 (File No. 001-36329).
10.17	Third Amendment to Credit Agreement and Release Agreement, dated as of October 22, 2019, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 8, 2019 (File No. 001-36329).
10.18	Fourth Amendment to Credit Agreement and Release Agreement, dated as of October November 5, 2020, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 10, 2020 (File No. 001-36329).
10.19	Fifth Amendment to Credit Agreement and Release Agreement, dated as of February 19, 2021, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 23, 2021 (File No. 001-36329).
10.20	Stock Issuance Agreement, dated as of February 19, 2021 by and between Recro Pharma, Inc., Athyrium Opportunities II Acquisition LP and Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 23, 2021 (File No. 001-36329).
10.21	Paycheck Protection Program Term Note dated May 12, 2020, between Recro Pharma, Inc. and PNC Bank, National Association.	Incorporated by reference to exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 15, 2020 (File No. 001-36329).
10.22	Common Stock Purchase Agreement, dated February 19, 2019, by and between Recro Pharma, Inc. and Aspire Capital Fund, LLC	Incorporated herein by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed on February 19, 2019 (File No. 001-36329).
10.23	First Amendment to the Common Stock Purchase Agreement, dated August 7, 2020, by and between Recro Pharma, Inc. and Aspire Capital Fund, LLC	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 10, 2020 (File No. 001-36329).
10.24•	Recro Pharma, Inc. 2018 Amended and Restated Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 9, 2018 (File No. 001-36329).
10.25•	Form of Award Agreement for Restricted Stock Unit Inducement Awards	Incorporated herein by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K filed on March 2, 2018 (File No. 001-36329).
10.26•	Form of Non-Qualified Stock Option Award Agreement	Filed herewith.
10.27•	Form of Award Agreement for Restricted Stock Units	Filed herewith.
10.28•	Form of Award Agreement for Restricted Stock Units (performance-based)	Filed herewith.
10.29•	Employment Agreement between Recro Pharma, Inc. and J. David Enloe, Jr., dated December 15, 2020.	Incorporated by reference to exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 21, 2020 (File No. 001-36329).
10.30•	Employment Agreement between Recro Pharma, Inc. and Ryan Lake, dated December 15, 2020.	Incorporated by reference to exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 21, 2020 (File No. 001-36329).

Exhibit No.	Description	Method of Filing
21.1	Subsidiaries of Recro Pharma, Inc.	Filed herewith.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.	Filed herewith.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101 SCH	Inline XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	Inline XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	Inline XBRL Taxonomy Extension Label Linkbase	Filed herewith.
101 PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	Filed herewith.

• Management contract or compensatory plan or arrangement.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

(c) Not applicable

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.

Date: February 26, 2021

RECRO PHARMA, INC.

By: /s/ J. David Enloe, Jr.
J. David Enloe, Jr.
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, Annual Report on Form 10-K has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ J. David Enloe, Jr. J. David Enloe, Jr.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2021
/s/ Ryan D. Lake Ryan D. Lake	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 26, 2021
/s/ William L. Ashton William L. Ashton	Director	February 26, 2021
/s/ Michael Berelowitz Michael Berelowitz	Director	February 26, 2021
/s/ Winston J. Churchill Winston J. Churchill	Director	February 26, 2021
/s/ Gerri A. Henwood Gerri A. Henwood	Director	February 26, 2021
/s/ James C. Miller James C. Miller	Director	February 26, 2021
/s/ Bryan M. Reasons Bryan M. Reasons	Director	February 26, 2021
/s/ Wayne B. Weisman Wayne B. Weisman	Director	February 26, 2021

RECRO PHARMA, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Recro Pharma, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Recro Pharma, Inc. and subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, shareholders' equity or deficit, and cash flows for each of the years in the three year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842) and ASU No. 2018-11, *Leases* (Topic 842), *Targeted Improvements*.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements 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 audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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 judgment. The communication of a critical audit matter 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 a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Variable consideration for profit-sharing revenue

As discussed in Note 2 to the consolidated financial statements, the Company earns sales-based profit-sharing or royalty consideration, collectively referred to as profit-sharing revenue, which is computed based on the net product sales of the commercial partner. For arrangements that include product sales and sales-based profit-sharing where the license for intellectual property is not deemed to be the predominant item to which the profit-sharing relates, the profit-sharing is variable consideration and the Company recognizes revenue, including an estimate of profit-sharing, upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions. Estimated variable consideration is partially constrained due to the uncertainty of price adjustments made by the Company's commercial partners, which are outside of the Company's control. Factors causing price adjustments by the Company's commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing.

We identified the evaluation of the estimate of the variable consideration for arrangements that include sales-based profit-sharing where the license for intellectual property is not deemed to be the predominant item as a critical audit matter. A high degree of auditor judgment was required to evaluate the Company's determination of the constraint due to the effect of market conditions and the uncertainty of price adjustments made by the Company's commercial partners.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and implementation of certain internal controls over the process for determining the estimate of variable consideration. We evaluated the Company's ability to estimate variable consideration by comparing the actual amount of profit-sharing revenue realized by the Company to its initial estimate. We obtained and inspected third party market data regarding the effect of market conditions on the commercial partners and potential price adjustments they may offer with respect to their products, as well as the Company, and assessed how the Company considered such market conditions in its determination of the constraint.

/s/ KPMG LLP

We have served as the Company's auditor since 2009.

Philadelphia, Pennsylvania
February 26, 2021

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 23,760	$ 19,148
Accounts receivable	9,033	14,389
Contract asset	7,330	8,851
Inventory	11,612	15,072
Prepaid expenses and other current assets	2,334	2,700
Total current assets	54,069	60,160
Property, plant and equipment, net	43,841	42,212
Intangible assets, net	700	3,283
Goodwill	4,319	4,319
Other assets	486	485
Total assets	$ 103,415	$ 110,459
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$ 1,804	$ 989
Accrued expenses and other current liabilities	4,525	4,324
Current portion of debt	1,474	—
Liabilities of discontinued operation	—	1,172
Total current liabilities	7,803	6,485
Debt, net	108,097	110,319
Other liabilities	1,615	367
Total liabilities	117,515	117,171
Commitments and contingencies (note 9)		
Shareholders' deficit:		
Preferred stock, $0.01 par value. 10,000,000 shares authorized, none issued or outstanding	—	—
Common stock, $0.01 par value. 50,000,000 shares authorized, 28,601,358 and 23,312,928 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	286	233
Additional paid-in capital	219,998	199,938
Accumulated deficit	(234,384)	(206,883)
Total shareholders' deficit	(14,100)	(6,712)
Total liabilities and shareholders' deficit	$ 103,415	$ 110,459

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(amounts in thousands, except share and per share data)	Year ended December 31, 2020	2019	2018
Revenue	$ 66,499	$ 99,219	$ 77,347
Operating expenses:			
Cost of sales (excluding amortization of intangible assets)	54,134	50,981	43,160
Selling, general and administrative	18,124	19,909	14,437
Research and development	—	—	4,402
Amortization of intangible assets	2,583	2,583	2,583
Change in warrant valuation	—	2,116	284
Total operating expenses	74,841	75,589	64,866
Operating (loss) income from continuing operations	(8,342)	23,630	12,481
Interest expense	(19,159)	(19,005)	(8,113)
(Loss) income from continuing operations before income taxes	(27,501)	4,625	4,368
Income tax expense	—	—	(17,436)
(Loss) income from continuing operations	(27,501)	4,625	(13,068)
Loss on discontinued operations	—	(23,255)	(66,655)
Net loss	$ (27,501)	$ (18,630)	$ (79,723)
(Loss) income per share information:			
Basic:			
Continuing operations	$ (1.16)	$ 0.21	$ (0.64)
Discontinued operations	—	(1.04)	(3.26)
Total	$ (1.16)	$ (0.83)	$ (3.90)
Weighted average shares outstanding	23,744,313	22,414,194	20,465,106
Diluted:			
Continuing operations	$ (1.16)	$ 0.20	$ (0.64)
Discontinued operations	—	(0.99)	(3.26)
Total	$ (1.16)	$ (0.79)	$ (3.90)
Weighted average shares outstanding	23,744,313	23,608,862	20,465,106

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Shareholders' Equity or Deficit

(amounts in thousands, except share data)	Common stock Shares	Common stock Amount	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance, December 31, 2017	19,127,435	$ 191	$ 140,006	$ (111,348)	$ (1)	$ 28,848
Cumulative effect of adoption of new revenue recognition standard	—	—	—	2,818	—	2,818
Issuance of common stock, net of costs	1,983,040	20	17,005	—	—	17,025
Stock-based compensation expense	—	—	7,129	—	—	7,129
Exercise of stock options, net	352,025	4	1,811	—	—	1,815
Vesting of restricted stock units, net	122,746	1	(92)	—	—	(91)
Exercise of warrants	214,715	2	2,587	—	—	2,589
Revaluation of warrants	—	—	89	—	—	89
Reclassification of other comprehensive loss to earnings	—	—	—	—	1	1
Net loss	—	—	—	(79,723)	—	(79,723)
Balance, December 31, 2018	21,799,961	218	168,535	(188,253)	—	(19,500)
Issuance of common stock for equity facility	34,762	—	301	—	—	301
Stock-based compensation expense	—	—	9,094	—	—	9,094
Exercise of stock options, net	863,952	9	5,994	—	—	6,003
Vesting of restricted stock units, net	429,926	4	(1,681)	—	—	(1,677)
Exercise of warrants	184,327	2	3,215	—	—	3,217
Separation of former Acute Care business (see note 3)	—	—	14,480	—	—	14,480
Net loss	—	—	—	(18,630)	—	(18,630)
Balance, December 31, 2019	23,312,928	233	199,938	(206,883)	—	(6,712)
Issuance of common stock, net of costs	4,690,972	47	10,686	—	—	10,733
Stock-based compensation expense	—	—	10,068	—	—	10,068
Exercise of stock options, net	142,669	1	273	—	—	274
Vesting of restricted stock units, net	454,789	5	(1,141)	—	—	(1,136)
Revaluation of warrants	—	—	174	—	—	174
Net loss	—	—	—	(27,501)	—	(27,501)
Balance, December 31, 2020	28,601,358	$ 286	$ 219,998	$ (234,384)	$ —	$ (14,100)

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

(amounts in thousands)	Year ended December 31, 2020	2019	2018
Cash flows from operating activities, continuing operations:			
Net loss	$ (27,501)	$ (18,630)	$ (79,723)
Loss on discontinued operations	—	23,255	66,655
Adjustments to reconcile income or loss from continuing operations to net cash provided by operating activities, continuing operations:			
Stock-based compensation expense	10,068	6,191	4,279
Non-cash interest expense	5,510	5,412	1,287
Depreciation expense	5,964	5,817	4,872
Impairment expense	966	—	—
Amortization of intangible assets	2,583	2,583	2,583
Change in warrant valuation	—	2,116	284
Deferred income taxes	—	—	17,637
Changes in operating assets and liabilities:			
Accounts receivable	5,356	(1,523)	(3,180)
Contract asset	1,521	(3,650)	(1,446)
Inventory	3,460	(4,373)	(860)
Prepaid expenses and other assets	4	(397)	(508)
Accounts payable, accrued expenses and other liabilities	1,308	(577)	(858)
Net cash provided by operating activities, continuing operations	9,239	16,224	11,022
Cash flows from investing activities, continuing operations:			
Purchases of property and equipment	(7,603)	(8,342)	(7,198)
Purchases of short-term investments	—	(12,100)	(6,225)
Proceeds from maturity of investments	—	12,100	9,750
Net cash used in investing activities, continuing operations	(7,603)	(8,342)	(3,673)
Cash flows from financing activities, continuing operations:			
Proceeds from issuance of common stock, net of costs	11,094	—	16,965
Cash contributed to former Acute Care business (see note 3)	—	(19,000)	—
Proceeds from issuance of debt, net of original issue discount of $11,400 for 2019	4,416	43,600	10,000
Repayments of debt	(10,190)	—	—
Payment of deferred financing costs	(310)	(2,936)	(961)
Net payments related to vesting of restricted stock units	(1,136)	(1,676)	(91)
Net proceeds related to exercise of stock options	274	6,003	1,815
Net cash provided by financing activities, continuing operations	4,148	25,991	27,728
Net increase in cash and cash equivalents from continuing operations	5,784	33,873	35,077
Discontinued operations:			
Cash flows used in operating activities	(1,172)	(41,721)	(54,137)
Cash flows used in investing activities	—	(1,518)	(3,410)
Cash flows used in financing activities	—	(10,000)	—
Net decrease in cash and cash equivalents from discontinued operations	(1,172)	(53,239)	(57,547)
Cash and cash equivalents, beginning of period	19,148	38,514	60,984
Cash and cash equivalents, end of period	$ 23,760	$ 19,148	$ 38,514
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 13,945	$ 14,395	$ 8,134
Purchases of property, plant and equipment included in accrued expenses and accounts payable	1,244	288	2,301
Common stock issued in connection with equity facility (see note 11)	—	301	357
Reclassification of deferred financing costs to equity	361	—	332

See accompanying notes to consolidated financial statements.

(1) Background

Recro Pharma, Inc. (the "Company") was incorporated in Pennsylvania onNovember 15, 2007. The Company is a dedicated contract development and manufacturing organization ("CDMO") solving complex formulation and manufacturing challenges for companies developing oral solid dose drug products. It leverages its formulation and development expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies and know-how for commercial partners who commercialize or plan to commercialize these products. The Company operates in one segment.

In November 2019, the Company's completed the spin-out of its former Acute Care business, which developed products for hospital and other acute care settings, as further described in note 3.

The Company has incurred net losses since inception and has an accumulated deficit of $234,384 as of December 31, 2020, which is mostly related to activities that are presented as discontinued operations as a result of the spin-off of its former Acute Care business into Baudax Bio. The Company's future operations are highly dependent on the continued profitability of its manufacturing operations. Management believes that it is probable that the Company will be able to meet its obligations as they become due within one year after the date the financial statements are issued.

(2) Summary of Significant Accounting Principles

(a) Basis of Presentation and Principles of Consolidation

The accompanying unaudited consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

(b) Use of Estimates

The preparation of financial statements and the notes to the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

(c) Cash and Cash Equivalents

Cash and cash equivalents represent cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near to their maturity that they present insignificant risk of changes in value because of the changes in interest rates.

(d) Property, Plant and Equipment

Property, plant and equipment are recorded at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to ten years for furniture, office and computer equipment; six to ten years for manufacturing equipment; 40 years for buildings; and the shorter of the lease term or useful life for leasehold improvements. Repairs and maintenance costs are expensed as incurred. The Company reviews the carrying value of property, plant and equipment for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of individual assets or asset groups may not be recoverable.

(e) Goodwill and Intangible Assets

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill is not amortized but assessed for impairment on an annual basis or more frequently if impairment indicators exist.

The impairment analysis for goodwill consists of an optional qualitative assessment potentially followed by a quantitative analysis. If we determine that the carrying value of the Company's reporting unit exceeds its fair value, an impairment charge is recorded for the excess.

Intangible assets include the Company's royalties and contract manufacturing relationships assets. The royalties and contract manufacturing relationships intangible asset is considered a definite-lived intangible asset and is amortized on a straight-line basis over a useful life of six years. The Company is required to review the carrying value of definite-lived intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

The Company performs its annual goodwill impairment test as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of goodwill. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance, anticipated changes in industry and market conditions, and competitive environments. The Company performed its last annual impairment test as of November 30, 2020 and noted that there have been no triggering events or indicators of impairment as of December 31, 2020. As a result of the impairment test, the Company determined that there was no impairment to goodwill for the year ended December 31, 2020.

(f) Revenue Recognition

The Company generates revenues from manufacturing, packaging, research and development and related services for multiple pharmaceutical companies. The agreements that the Company has with its commercial partners provide for manufacturing revenues, sales-based royalties and/or profit-sharing components.

Manufacturing Revenue

Manufacturing and other related services revenue is recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration the Company expects to be entitled to as specified in the agreement with the commercial partner, which could include pricing and volume-based adjustments.

Profit-sharing Revenue

In addition to manufacturing and packaging revenue, certain customer agreements may have intellectual property sales-based profit-sharing and/or royalties consideration, collectively referred to as profit-sharing, computed on the net product sales of the commercial partner. Profit-sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based profit-sharing where the license for intellectual property is deemed to be the predominant item to which the profit-sharing relates, the Company recognizes revenue when the related sales occur by the commercial partner. For arrangements that include sales-based profit-sharing where the license for intellectual property is not deemed to be the predominant item to which the profit-sharing relates, the Company recognizes revenue upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions. Estimated variable consideration is partially constrained due to the uncertainty of price adjustments made by the Company's commercial partners, which are outside of the Company's control. Factors causing price adjustments by the Company's commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing.

Research and Development

Research and development revenue includes services associated with formulation, process development, clinical trials materials services, as well as custom development of manufacturing processes and analytical methods for a customer's non-clinical, clinical and commercial products. Such revenues are recognized at a point in time or over time depending on the nature and particular facts and circumstances associated with the contract terms.

In contracts that specify milestones, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which the Company has continuing performance obligations are deferred and recognized over the period of performance. Milestone payments that are not withinthe Company's control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

In contracts that require revenue recognition over time, the Company utilizes input or output methods, depending on the specifics of the contract, that compare the cumulative work-in-process to date to the most current estimates for the entire performance obligation. Under these contracts, the customer typically owns the product details and process, which have no alternative use. These projects are customized to each customer to meet its specifications and typically only one performance obligation is included. Each project represents a distinct service that is sold separately and has stand-alone value to the customer. The customer also retains control of its product as the product is being created or enhanced by the Company's services and can make changes to its process or specifications upon request.

(g) Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and accounts receivable. The Company manages its cash and cash equivalents based on established guidelines relative to diversification and maturities to maintain safety and liquidity.

The Company's accounts receivable balances are primarily concentrated amongthree customers. If any of these customers' receivable balances should be deemed uncollectible, it could have a material adverse effect on the Company's results of operations and financial condition.

The Company is dependent on its relationships with a small number of commercial partners, with itsthree largest customers having generated 90% or more of its revenues for the periods presented.

(h) Stock-based Compensation Expense

The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award. The Company accounts for forfeitures as they occur.

Determining the appropriate fair value of stock options requires the input of subjective assumptions, including the expected life of the option and expected stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and/or management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," which is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses the historical volatility of its publicly traded stock in order to estimate future stock price trends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

Upon exercise of stock options or vesting of restricted stock units, the holder may elect to cover tax withholdings by forfeiting shares of an equivalent value. In such cases, the Company issues net new shares to the holder, pays the tax withholding on behalf of the participant and presents the payment similar to a capital distribution: a reduction to additional paid-in-capital and a financing cash outflow in the consolidated financial statements.

For non-employee stock-based awards, the Company recognizes compensation expense on a straight-line basis over the vesting period of each separated vesting tranche of the award, which is known as the accelerated attribution method. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, such amounts are recognized as an adjustment in the period in which estimates are revised.

(i) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized. A full valuation allowance was recorded as of December 31, 2020 and December 31, 2019.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the consolidated financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

(j) Income or Loss Per Share

Basic income or loss per share is determined by dividing net income or loss (the numerator) by the weighted average common shares outstanding during the period (the denominator).

To calculate diluted income or loss per share, the numerator and denominator are adjusted to eliminate the income or loss and the dilutive effects on shares, respectively, caused by outstanding common stock options, warrants and unvested restricted stock units, using the treasury stock method, if the inclusion of such instruments would be dilutive.

For the periods presented, only the denominator of 2019 basic income per share was adjusted for the dilutive effects described above. The following table presents those effects:

	Year ended December 31, 2019
Weighted average shares outstanding, basic	22,414,194
Dilutive impact of:	
Restricted stock units	377,852
Stock options	673,364
Warrants	143,452
Weighted average shares outstanding, diluted	23,608,862

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	Year ended December 31,		
	2020	2019	2018
Restricted stock units	684,852	29,897	605,626
Stock options	3,577,605	1,963,760	3,402,415
Warrants	348,664	—	838,664

Amounts in the table above reflect the common stock equivalents of the noted instruments.

(k) Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

On January 1, 2018, the Company adopted a comprehensive new five-step framework for revenue recognition, ASU 2014-09,*Revenue from Contracts with Customers (Topic 606),* using the modified retrospective method. Topic 606 replaced prior revenue recognition guidance. The Company recognized a $2,818 cumulative-effect adjustment upon adoption of Topic 606 to establish contract assets and liabilities in accordance with the standard. No prior periods were restated. All periods included in the financial statements are presented in accordance with Topic 606.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*," or ASU 2016-02. ASU 2016-02 introduced a new lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), *Targeted Improvements*, which provided an alternative transition method permitting the recognition of a cumulative-effect adjustment on the date of adoption rather than restating comparative periods in transition as originally prescribed by Topic 842. The Company adopted this guidance as of January 1, 2019. The Company elected the optional transition method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company opted to elect the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs, and certain other practical expedients, including the use of hindsight to determine the lease term for existing leases and in assessing impairment of the right-of-use asset, and the exception for short-term leases. For its current classes of underlying assets, the Company did not elect the practical expedient under which the lease components would not be separated from the nonlease components. At January 1, 2019, the Company recorded a right -of-use asset of $692 and an operating lease liability of $728.

On January 1, 2020, the Company adopted ASU 2018-13, "*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,*" or ASU 2018-13. ASU 2018-13 removes, modifies and adds certain disclosure requirements in Topic 820 "*Fair Value Measurement*". There was no impact upon adoption because the Company is not currently required to provide any of the disclosures impacted by the new standard.

On January 1, 2021, the Company adopted ASU No. 2016-13, "*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,"* or ASU 2016-13, a new standard for measuring expected credit losses. That guidance impacts the measurement of doubtful accounts receivable, among other things. The adoption had no impact to our consolidated financial statements.

(3) Discontinued Operations

On November 21, 2019 (the "Distribution Date"), the Company completed the separation (the "Separation") of its former Acute Care business by distributing to the Company's shareholders on a pro rata basis all of the issued and outstanding common stock of Baudax Bio, the entity the Company incorporated to hold such businesses. To effect the Separation, the Company distributed to its shareholders 1 share of Baudax Bio common stock for every 2.5 shares of the Company's common stock outstanding as of November 15, 2019, the record date for the distribution. Additionally, in connection with the Separation, the Company contributed $19,000 of cash to Baudax Bio.

In connection with the Separation, the Company and Baudax Bio entered into various agreements to effect the Separation and provide a framework for their relationship after the Separation, including a transition services agreement, an employee matters agreement, a tax matters agreement and an intellectual property matters agreement. These agreements provide for the allocation between the Company and Baudax Bio of assets, employees, liabilities and obligations (including investments, property and employee benefits and tax-related assets and liabilities) attributable to periods prior to, at, and after Baudax Bio's separation from the Company and govern certain relationships between the Company and Baudax Bio after the Separation.

The accounting requirements for reporting the Separation of Baudax Bio as a discontinued operation were met when the Separation was completed. Accordingly, the accompanying consolidated financial statements for all periods presented reflect the Acute Care business as a discontinued operation, except for certain corporate overhead costs and certain costs associated with transition services provided by Baudax Bio to the Company following the Separation, which are included in continuing operations.

At December 31, 2019, the current liability of discontinued operation was $1,172 and consisted almost entirely of accrued expenses paid in early 2020.

The following table presents the expenses of the Acute Care business that are included within loss on discontinued operations:

	Year ended December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 19,471	$ 35,583
Selling, general and administrative	18,441	22,441
Change in contingent consideration valuation	(14,783)	8,499
Total operating expenses	23,129	66,523
Other expense, net	(126)	(132)
Loss on discontinued operations	$ (23,255)	$ (66,655)

(4) Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, "*Fair Value Measurements and Disclosures*," for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, short-term investments and certain warrants. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2: Inputs that are other than quoted prices in active markets for identical assets and liabilities, inputs that are quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are either directly or indirectly observable; and
- Level 3: Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Items measured at fair value on a recurring basis

Cash equivalents of $6,583 and $11,609 at December 31, 2020 and 2019, respectively, consisted entirely of money market mutual funds whose fair value were determined using Level 1 measurements.

The reconciliation of warrants measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	Warrants
Balance at December 31, 2017	$ 3,406
Exercise of warrants	(2,589)
Remeasurement	284
Balance at December 31, 2018	$ 1,101
Exercise of warrants	(3,217)
Remeasurement	2,116
Balance at December 31, 2019	$ —

Fair value disclosures

The Company follows the disclosure provisions of FASB ASC Topic 825, "*Financial Instruments*" (ASC 825), for disclosure purposes for financial assets and financial liabilities that are not measured at fair value. As of December 31, 2020, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable and accrued expenses and approximate fair value due to the short-term nature of these instruments.

The fair value of long-term debt, where a quoted market price is not available, is evaluated based on, among other factors, interest rates currently available to the Company for debt with similar terms, remaining payments and considerations of the Company's creditworthiness. The Company determined that the recorded book value of its debt, a level 2 measurement, approximated fair value at December 31, 2020 as (i) the terms of borrowings under the Credit Agreement are equivalent to the terms of other borrowings currently available to the Company through its recently completed debt refinancing process; and (ii) the fair value of the PPP Note, which carries a fixed interest rate below market, is not materially different from its carrying value.

(5) Inventory

Inventory is stated at the lower of cost and net realizable value. Included in inventory are raw materials and work-in-process used in the production of commercial products. Items are issued out of inventory using the first-in, first-out method.

Inventory was as follows:

	December 31, 2020	December 31, 2019
Raw materials	$ 3,373	$ 3,240
Work in process	5,061	6,430
Finished goods	3,544	5,892
Inventory, prior to provision	11,978	15,562
Provision for inventory obsolescence	(366)	(490)
Inventory	$ 11,612	$ 15,072

Adjustments to inventory are determined at the raw materials, work-in-process, and finished good levels to reflect obsolescence or impaired balances. Inventory is primarily ordered to meet specific customer orders and largely reflects demand. Factors influencing inventory obsolescence include changes in demand, product life cycle, product pricing, physical deterioration and quality concerns.

(6) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31, 2020	December 31, 2019
Land	$ 3,263	$ 3,263
Building and improvements	20,924	20,900
Furniture, office and computer equipment	5,879	5,847
Manufacturing equipment	39,349	35,699
Construction in progress	5,568	729
Property, plant and equipment, gross	74,983	66,438
Less: accumulated depreciation	(31,142)	(24,226)
Property, plant and equipment, net	$ 43,841	$ 42,212

For the year ended December 31, 2020, depreciation expense includes $966 of impairment expense related to assets associated with a discontinued product, and $301 of interest expense was capitalized to construction in process.

(7) Intangible Assets

The following table presents the components of our profit-sharing and contract manufacturing relationships asset, which was the only class of intangible asset for the periods presented:

	December 31, 2020	December 31, 2019
Cost	$ 15,500	$ 15,500
Accumulated amortization	(14,800)	(12,217)
Net intangible assets	$ 700	$ 3,283

At December 31, 2020, remaining amortization expense of $700 is scheduled to be recognized in 2021.

(8) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2020	December 31, 2019
Payroll and related costs	$ 1,481	$ 2,958
Current portion of contract liabilities (see note 12)	1,447	337
Property, plant and equipment	551	88
Professional and consulting fees	432	370
Other	614	571
Total	$ 4,525	$ 4,324

(9) Commitments and Contingencies

Litigation

The Company is involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. Except as disclosed below, the Company is not currently a party to any such claims or proceedings that, if decided adversely to it, would either individually or in the aggregate have a material adverse effect on its business, financial condition or results of operations.

On May 31, 2018, a securities class action lawsuit (the "Securities Litigation") was filed against the Company and certain of its officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by the Company concerning the New Drug Application ("NDA") for IV meloxicam. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. On December 10, 2018, the lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers as defendants. On February 8, 2019, the Company filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, the Company filed its response and briefing was completed on the motion to dismiss. In response to questions from the Judge, the parties submitted supplemental briefs with regard to the motion to dismiss the amended complaint during the fall of 2019. On February 18, 2020, the motion to dismiss was granted without prejudice. On April 25, 2020, the plaintiff filed a second amended complaint. The Company filed a motion to dismiss the second amended complaint on June 18, 2020. The plaintiff filed an opposition to the Company's motion to dismiss on August 17, 2020. On September 16, 2020, the Company filed a reply in support of its motion to dismiss. In connection with the separation of Baudax Bio, Baudax Bio accepted assignment by the Company of all of its obligations in connection with the Securities Litigation and agreed to indemnify it for all liabilities related to the Securities Litigation. The Company and Baudax Bio believe that the lawsuit is without merit and intend to vigorously defend against it.

Purchase Commitments

As of December 31, 2020, the Company had outstanding non-cancelable purchase commitments in the aggregate amount of $3,641 related to inventory, capital expenditures and other goods and services.

Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers that provide for, among other things, severance commitments should the Company terminate the named executive officers for convenience or if certain events occur following a change in control. The Company's potential payments to executives under those agreements was $1,250 at December 31, 2020.

(10) Debt

The carrying value of debt consists of the following as of December 31, 2020:

	Term loans under Credit Agreement	PPP Note	Total
Principal balance outstanding	$ 116,000	$ 3,316	$ 119,316
Unamortized deferred issuance costs	(10,359)	—	(10,359)
Exit fee accretion	614	—	614
Total debt	106,255	3,316	109,571
Current portion of debt	—	(1,474)	(1,474)
Debt, net	$ 106,255	$ 1,842	$ 108,097

The following table presents the maturity of debt principal as of December 31, 2020 (including exit fee):

	Term loans under Credit Agreement	PPP Note	Total
2021	$ —	$ 1,474	$ 1,474
2022	12,120	1,842	13,962
2023	105,040	—	105,040
Total debt	$ 117,160	$ 3,316	$ 120,476

Term Loans under Credit Agreement

The Company is currently party to a credit agreement (the "Credit Agreement") with Athyrium Opportunities III Acquisition LP ("Athyrium"). On February 19, 2021, we amended the Credit Agreement as described in note 18. The amendment changed many of the terms of the Credit Agreement described below, all of which are as of or for periods through December 31, 2020.

The Credit Agreement has been fully drawn in the form of term loans. The Company was required to repayquarterly installments of $3,030 beginning on March 31, 2022, with the remaining outstanding principal balance plus exit fee due onMarch 31, 2023.

The Credit Agreement was amended from time to time. The most recent amendment in November 2020 resulted in the prepayment without penalty of$9,000 principal and a $90 exit fee in addition to certain changes to the terms of the debt.

The term loans under the Credit Agreement included a rate ofinterest equal to the three-month LIBOR rate, with a1% floor plus 9.75% per annum. The term loans require the Company to pay a 1% exit fee on all repayments, which was, in the aggregate, $1,160 at December 31, 2020. The cumulative exit fee accreted as of December 31, 2020 is $614. The exit fees are being accreted to the carrying amount of the debt using the effective interest method over the term of the loan. In addition, if there is an early repayment, there is a sliding scale of prepayment penalties beginning with a10% penalty and including a make-whole interest payment. No prepayment penalties are assessed for payments made after March 31, 2022.

The Credit Agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants that the Company will need to satisfy on a monthly and quarterly basis, including maintaining a permitted leverage ratio (which is the Company's indebtedness under the Credit Agreement divided by EBITDA, each as defined in the Credit Agreement) and liquidity amount. As of December 31, 2020, the Company was in compliance with its covenants under the Credit Agreement.

In connection with the Credit Agreement, the Company issued warrants to each of Athyrium and its affiliate, Athyrium Opportunities II Acquisition LP ("Athyrium II"), to purchase an aggregate of 348,664 shares of the Company's common stock with a current exercise price of $1.73 per share. See note 11 for additional information. The warrants are exercisable through November 17, 2024.

In connection with the Credit Agreement and four subsequent amendments, the Company has paid financing costs, has incurred costs to record and subsequently adjust the value of the warrants described above and has been accreting the exit fee described above. These costs are being recognized in interest expense using the effective interest method over the term of the Credit Agreement, resulting in $5,510, $5,412 and $1,287 of non-cash interest expense in 2020, 2019 and 2018, respectively.

At December 31, 2020, the overall effective interest rate, including cash paid for interest and non-cash interest expense, was15.04%.

Paycheck Protection Program ("PPP") Note

On May 12, 2020, the Company entered into a $4,416 promissory note with PNC Bank under the Small Business Administration ("SBA") Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act," collectively the "PPP Note"). On May 18, 2020, the Company prepaid $ 1,100 of the note in order to comply with the SBA's limitations on the amount that could be borrowed at that time.

The note has a two-year term, matures on May 12, 2022 and bears interest at a stated rate of1.0% per annum. However, principal and interest due under the note may be forgiven in part or in whole if the Company meets certain requirements described below. To the extent not forgiven, monthly principal and interest payments would commence on the earlier of September 15, 2021 or the date on which a forgiveness decision is received from PNC Bank. The note requires no collateral or guarantees, nor did the Company pay any fees to acquire the note. The note provides for customary events of default, including, among others, failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company may prepay principal at any time without incurring any prepayment charges.

The PPP Note may be partially or fully forgiven if the Company complies with the provisions of the CARES Act, including the use of note proceeds for payroll costs, rent, utilities and other expenses, and at least 60% of the note proceeds must be used for payroll costs as defined by the CARES Act. Any forgiveness of the note will be subject to approval by both the SBA and PNC Bank of an application for forgiveness, which the Company submitted on October 6, 2020. SBA and PNC Bank are currently required to provide the Company a forgiveness decision during the first half of 2021. Should the Company meet the requirements for forgiveness, it would extinguish the note upon receiving legal release from PNC Bank and record a gain on extinguishment in that period.

(11) Shareholders' Equity or Deficit

Capital raises

The following table presents the Company's capital raises since its initial public offering:

	Date or period	Shares of common stock issued	Gross proceeds	Offering expenses	Net proceeds
Initial public offering	March 12, 2014	4,312,500	$ 34,500	$ (4,244)	$ 30,256
Private placement	July 7, 2015	1,379,311	16,000	(1,188)	14,812
Underwritten public offering	August 19, 2016	1,986,666	14,900	(1,533)	13,367
Underwritten public offering	December 16, 2016	6,670,000	40,020	(3,132)	36,888
2018 common stock purchase agreement	Year ended December 31, 2018	1,950,000	16,999	—	16,999
2019 common stock purchase agreement	Fourth quarter 2020	4,690,972	11,172	(78)	11,094

Aspire Common Stock Purchase Agreements

The Company is currently party to an amended common stock purchase agreement with Aspire Capital Fund LLC ("Aspire Capital") originally entered into during 2019. The amended agreement provided that, upon the terms and subject to the conditions and limitations set forth in the agreement, Aspire Capital was committed to purchase, at the Company's sole election, up to an aggregate of $30,000 or 4,690,972 additional shares of common stock. From November 10 to December 29, 2020, all available shares were sold under the agreement at a discount of 3.2% the average closing stock price over that period. Previously, the Company was party to a common stock purchase agreement entered into during 2018.

In connection with entering into these agreements, the Company issued commitment shares to Aspire Capital of 34,762 with a fair value of $301 in 2019 and 33,040 with a fair value of $357 in 2018. No additional shares were available to issue under the common stock purchase agreements at December 31, 2020.

Warrants

At December 31, 2020, warrants to purchase 348,664 shares of common stock were outstanding. The warrants are held by Athyrium, equity-classified, exercisable at $1.73 per share and expire in November 2024.

In November 2019, the warrant to purchase 350,000 shares issued to Alkermes plc, which was liability classified as it contained a contingent net cash settlement feature, was exercised on a cashless basis, with Alkermes plc surrendering 165,673 shares to cover the aggregate exercise price, resulting in the issuance of 184,327 shares of common stock based on the closing bid price of the Company's common stock on November 8, 2019 of $17.45.

(12) Revenue Recognition

Contract assets represent revenue recognized for performance obligations completed before an unconditional right to payment exists, and therefore invoicing or associated reporting from the customer regarding the computation of the net product sales has not yet occurred. Generally, the contract assets balance is impacted by the recognition of additional contract assets, offset by amounts invoiced to customers or actual net product sale amounts reported by the commercial partner for the period.

The following table presents changes in contract assets and liabilities:

	Contract assets	Contract liabilities
Balance at December 31, 2019	$ 8,851	$ 337
Changes to the beginning balance of contract assets arising from:		
Reclassification to receivables as a result of rights to consideration becoming unconditional	(13,496)	—
Changes in estimate	4,645	—
Contract assets recognized since beginning of period, net of reclassification to receivables and changes in estimates	7,330	—
Changes to contract liabilities:		
Cash received in advance of contract performance	—	7,241
Revenue recognized	—	(4,883)
Balance at December 31, 2020	$ 7,330	$ 2,695
Less: noncurrent portion	—	(1,248)
Current portion	$ 7,330	$ 1,447

The following table disaggregates revenue by timing of revenue recognition:

	Year ended December 31,		
	2020	2019	2018
Point in time	$ 61,616	$ 96,346	$ 76,270
Over time	4,883	2,873	1,077
Total	$ 66,499	$ 99,219	$ 77,347

The Company's payment terms for manufacturing revenue and development services are typically 30 to 45 days. Profit-sharing revenue is recorded to accounts receivable in the quarter that the product is sold by the commercial partner upon reporting from the commercial partner and payment terms are generally 45 days after quarter end.

(13) Retirement Plan

The Company has a voluntary 401(k) savings plan in which all employees are eligible to participate. The Company's policy is to match100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan were $941 for 2020, $926 for 2019 and $860 for 2018.

(14) Stock-Based Compensation

In October 2013, the Company established an equity incentive plan that has been subsequently amended and restated to become the 2018 Amended and Restated Equity Incentive Plan (the "A&R Plan") At December 31, 2020, a total of 3,923,453 shares were available for future grants under the A&R Plan. On December 1st of each year, pursuant to the "Evergreen" provision of the A&R Plan, the number of shares available under the A&R Plan may be increased by the board of directors by an amount equal to 5% of the outstanding common stock on December 1st of that year.

Stock options

Stock options are exercisable generally for a period of10 years from the date of grant and generally vest overfour years.

The following table presents information about the fair value of stock options granted:

	Year ended December 31,		
	2020	2019	2018
Weighted average grant date fair value	$ 5.14	$ 5.72	$ 5.95
Assumptions used to determine fair value:			
Range of expected option life	5.5 - 6 years	5.5 - 6 years	5.5 - 6 years
Expected volatility	75 - 81%	78 - 82%	73 - 82%
Risk-free interest rate	0.3 - 1.4%	1.6 - 2.7%	2.3 - 3.0%
Expected dividend yield	—	—	—

The intrinsic value of options exercised was $1,058 in 2020, $5,227 in 2019 and $1,322 in 2018.

The following table presents information about recent stock option balances and activity:

	Number of shares	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life
Balance, December 31, 2019	3,695,649	$ 7.97		
Granted	692,430	7.66		
Exercised	(178,747)	4.52		
Forfeited or expired	(302,322)	8.55		
Balance, December 31, 2020	3,907,010	8.03	$ 76	6.8 years
Exercisable	2,610,656	8.22	56	5.8 years

Included in the table above are 571,175 options outstanding as of December 31, 2020 that were granted outside the A&R Plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

Restricted stock units

Restricted stock units ("RSUs") vest over six months to four years depending on the purpose of the award. The fair value of RSUs on the date of grant is measured as the closing price of our common stock on that date. The weighted average grant-date fair value of RSUs awarded to employees was $5.34 in 2020, $10.95 in 2019 and $7.97 in 2018. The fair value of RSUs vested was $4,039 in 2020, $6,030 in 2019 and $1,351 in 2018, respectively.

The following table presents information about recent RSU activity:

	Number of shares	Weighted average grant date fair value
Balance, December 31, 2019	1,197,502	$ 10.92
Granted	1,258,409	5.34
Vested	(593,701)	13.28
Forfeited	(345,391)	9.55
Balance, December 31, 2020	1,516,819	5.67

Included in the table above are 227,447 time-based RSUs outstanding at December 31, 2020 that were granted outside of the A&R Plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

Other information

The following table presents the classification of stock-based compensation expense:

	Year ended December 31,		
	2020	2019	2018
Cost of sales	$ 3,754	$ 1,753	$ 1,034
Selling, general and administrative expenses	6,314	4,438	3,064
Research and development	—	—	181
Continuing operations	$ 10,068	$ 6,191	$ 4,279
Discontinued operations	—	2,903	2,850
Total	$ 10,068	$ 9,094	$ 7,129

For the year ended December 31, 2020, stock-based compensation expense included awards issued to the Company's employees as well as Baudax Bio employees that provided services to the Company through the transition services agreement and certain other related agreements (see note 3). In accordance with the terms of those agreements, the Recro equity grants held by such former employees continued to vest in accordance with their respective vesting schedules. Any stock-based compensation expense with respect to former employees who continue to vest based on their employment service at Baudax Bio but no longer provide services to the Company is not reflected in the Company's financial statements.

As of December 31, 2020, there was $8,769 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 2.7 years. As of December 31, 2020, there was $2,624 of unrecognized compensation expense related to unvested performance-based RSUs.

(15) Income Taxes

All of the Company's income from continuing operations is domestic. The components of the income tax provision from continuing operations are as follows:

	Year ended December 31,		
	2020	2019	2018
Current:			
Federal	$ —	$ —	$ (130)
State and local	—	—	1
Total current	—	—	(129)
Deferred:			
Federal	(5,539)	1,368	124
State and local	(1,596)	(356)	(1,327)
Total deferred	(7,135)	1,012	(1,203)
Change in valuation allowance	7,135	(1,012)	18,768
Income tax expense	$ —	$ —	$ 17,436

A reconciliation of the statutory U.S. federal income tax rate to the Company's effective tax rate from continuing operations is as follows:

	Year ended December 31,		
	2020	2019	2018
U.S. federal statutory income tax rate	21 %	21 %	21 %
State taxes, net of federal benefit	6 %	(8)%	(30)%
Nondeductible expenses	(1)%	11 %	—
Research and development credits	—	(3)%	(21)%
Change in valuation allowance	(26)%	(22)%	430 %
Other	—	1 %	(1)%
Effective income tax rate	—	—	399 %

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows:

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 37,127	$ 35,052
Interest expense	11,380	6,966
Stock-based compensation	4,683	4,441
Research and development credits	4,443	4,443
Capitalized start-up costs	1,438	1,588
Other temporary differences	1,194	828
Gross deferred tax asset	60,265	53,318
Valuation allowance	(52,349)	(45,214)
Net deferred tax asset	7,916	8,104
Deferred tax liabilities:		
Depreciation	(5,511)	(5,308)
Deferred revenue	(2,084)	(2,533)
Other	(321)	(263)
Deferred tax liability	(7,916)	(8,104)
Net deferred taxes	$ —	$ —

The net deferred tax asset and deferred tax liability shown in the table above are each noncurrent and offset one another for financial reporting purposes, resulting in no presentation on the consolidated balance sheet.

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards.

In 2018, the Company recorded a valuation allowance against its U.S. and state deferred tax assets based on the available positive and negative evidence available. An important aspect of objective negative evidence evaluated was the Company's historical operating results over the prior three-year period. The Company maintains the valuation allowance as of December 31, 2020 as a result of historical losses, inclusive of discontinued operations, during the most recent three-year period. The Company will re-evaluate the need for a valuation allowance in future periods based on its operating results as a standalone entity.

The following table summarizes carryforwards of Federal net operating losses and tax credits as of December 31, 2020:

	Amount	Expiration
Federal net operating losses, 2008 to 2017	$ 8,200	2028 – 2037
Federal net operating losses, 2018 to 2020	122,418	No expiration
State net operating losses	127,368	2028 – 2040
Federal and state research and development credits	4,360	2028 – 2039

Under the Tax Reform Act of 1986, as amended (the "Act"), the utilization of a corporation's net operating loss and research and development tax credit carryforwards is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. The Company has done an analysis to determine whether or not ownership changes, as defined by the Act, have occurred since inception. The Company determined that it experienced ownership changes, as defined by the Act, during the 2008, 2014 and 2016 tax years as a result of past financings; accordingly, the Company's ability to utilize the aforementioned carryforwards will be limited. In addition, state net operating loss carryforwards may be further limited, including in Pennsylvania, which has a limitation of 40% of taxable income after modifications and apportionment on state net operating losses utilized in any one year during tax years beginning 2019.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2020, the Company had no accrued interest or penalties related to uncertain tax positions, and no amounts have been recognized in the Company's statements of operations. Due to net operating loss and tax credit carry forwards that remain unutilized, income tax returns for tax years from inception through 2020 remain subject to examination by the taxing jurisdictions.

(16) Leases

The Company determines if an arrangement is a lease at inception. The arrangement is a lease if it conveys the right to the Company to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Options to extend the lease are included in the lease term if the options are reasonably certain to be exercised. Operating lease expense is recognized on a straight-line basis over the lease term.

The following table presents the operating lease amounts recognized on our consolidated balance sheets:

		December 31,	
	Balance sheet classification	2020	2019
Asset	Other assets	$ 486	$ 485
Liabilities:			
Current	Accrued expenses and other current liabilities	145	148
Noncurrent	Other liabilities	366	367

The Company is a party to a seven-year operating lease for a development facility in Georgia that ends in 2025 and immaterial operating leases for a storage area and office equipment. The development facility lease includes options to extend the lease for up to 15 additional years, none of which are included in the lease term. Short-term and variable lease costs were not material for the periods presented. The development facility lease does not provide an implicit rate, so the Company uses its incremental borrowing rate to discount the lease liability.

Undiscounted future lease payments for the development lease, which was the only material noncancelable lease at December 31, 2020, were as follows:

	December 31, 2020
2021	$ 156
2022	156
2023	156
2024	156
2025 and thereafter	91
Total lease payments	715
Less imputed interest	(204)
Total operating lease liabilities	$ 511

At December 31, 2020, the weighted average remaining lease term was 4.5 years, and the weighted average discount rate was 16%. Total lease cost was $310 for 2020 and $306 for 2019.

(17) Related Party Transactions

Baudax Bio became a related party to the Company following the Separation. As part of the Separation, the Company entered into a transition services agreement with Baudax Bio. Under the transition services agreement, Baudax Bio provides certain services to the Company, each related to corporate functions, which are charged to the Company. Additionally, the Company may incur expenses that are directly related to Baudax Bio after the Separation, which are billed to Baudax Bio. As a result of these activities, the Company was due $65 from and owed $273 to its former Acute Care business at December 31, 2020 and 2019, respectively.

During 2020 and 2019, the Company recorded expense of $1,964 and $206 related to its transition services agreement with Baudax Bio. These expenses are classified as selling, general and administrative expenses.

(18) Subsequent events

On February 19, 2021, the Company entered into the Fifth Amendment to Credit Agreement and Investment Documents (the "Fifth Amendment") with Athyrium (see note 10). The Fifth Amendment provides for (i) the repayment by the Company of $16.0 million of the outstanding principal amount of the loans issued under the Credit Agreement, (ii) a reduction of the interest rate on the remaining loans outstanding, and (iii) permits an equity issuance in connection with the Fifth Amendment. The Fifth Amendment also changes certain other terms and covenants contained the Credit Agreement that allow the Company to pursue additional acquisitions as well as easing certain requirements surrounding the financial covenants, including the liquidity the Company is required to maintain as well as the threshold for compliance with the consolidated leverage ratio.

On February 19, 2021, the Company entered into a Stock Issuance Agreement (the "Stock Issuance Agreement") with Athyrium for the sale by the Company in a private placement of 2,202,420 of the Company's common stock as consideration for Athyrium's entrance into the Fifth Amendment and reduction in the amount of principal and interest outstanding under the Credit Agreement and payments of accrued and unpaid interest and an exit fee in an aggregate amount equal to $9,360,285.

Exhibit 10.26

Recro Pharma, Inc.
2018 Amended And Restated Equity Incentive Plan
Non-Qualified Stock Option Award Agreement

We are pleased to advise you that Recro Pharma, Inc. (the "Company") hereby awards to you, under the Recro Pharma, Inc. 2018 Amended and Restated Equity Incentive Plan (the "Plan"), the right to purchase (an "Option") the number of shares of Common Stock of the Company ("Shares"), as set forth on the grant schedule attached hereto (the "Grant Schedule"), subject to your signing this Award Agreement (this "Agreement"). The date of award of the Option shall for all purposes be the date set forth on the Grant Schedule (the "Grant Date"). The Option issued hereunder are "non-qualified stock options" for tax purposes.

This award is subject in all respects to the applicable provisions of the Plan, a complete copy of which has been furnished to you and receipt of which you acknowledge by acceptance of the award. Such provisions are incorporated herein by reference and made a part hereof (including all defined terms).

All capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan. In addition to the terms, conditions and restrictions set forth in the Plan, all terms, conditions and restrictions set forth in this Agreement and the Grant Schedule are applicable to the Option evidenced hereby.

1. ***Vesting***

. Subject to the further provisions of this Agreement and your continued service with the Company through each applicable vesting date, the Option awarded by this Agreement shall become vested and exercisable in such amounts and at such times as are set forth on the Grant Schedule (each date on which any portion of the Option vests being referred to as a "Vesting Date"). In addition, any unvested portion of the Option shall become immediately and fully vested upon your death or Disability, provided you continue in service with the Company through the date of such event. For purposes of this Agreement, service with the Company will include service with an Affiliate (for only so long as such entity remains an Affiliate).

2. ***Expiration of Option***

. Your Option, whether vested or unvested, shall expire on the earliest to occur of the following:

(a) three months after cessation of your service with the Company for any reason other than death, Disability, or Cause;

(b) one year after cessation of your service with the Company due to your death or Disability;

(c) the date and time of any cessation of your service with the Company for Cause;

(d) the tenth anniversary of the Grant Date; and

(e) if so determined by the Board in its discretion, upon the occurrence of a Change in Control.

3. ***Exercise of Option***

.

(a) The exercise price for each Share under your Option shall be as set forth in the Grant Schedule (the "Option Price").

(b) The Option may be exercised only to the extent it is vested. To exercise any vested portion of the Option, you must (i) provide the Company with written notice of your intention to exercise the Option and the number of Shares you intend to acquire, (ii) execute a counterpart to any shareholders agreement or other agreement required to be executed by optionees generally, and (iii) deliver a check for the Option Price multiplied by the number of Shares being acquired or such other manner of payment as approved by the Company. As an alternative to delivering a check, you may choose to exercise any vested Option hereunder on a "cashless" basis. Under this method, you do not have to remit the Option Price under the Option in cash. Instead, the Option Price is paid by reducing the number of Shares otherwise issuable to you upon exercise by such number of Shares having a Fair Market Value (determined at the time of exercise) equal to the Option Price. You shall only have rights as a shareholder of the Company with respect to Shares which have been issued after the Option has vested and been exercised.

4. ***Withholding***

. The Company shall have the right to withhold all applicable income and employment taxes on the date of exercise or cash-out of the Option, or such other date as required by the Code. If there is insufficient compensation due from the Company to you at the time such withholding is due, the Company shall have the right, as a condition to the exercise of the Option and prior to delivery of any Shares, to require you to remit to the Company an amount equal to the excess of your share of the income and employment taxes subject to withholding over the amount of compensation then due from the Company to you.

5. ***Registration of Shares***

. The Company may postpone the issuance and delivery of any Shares until the completion or amendment of any registration or qualification of the Shares under any federal or state law, rule or regulation which the Company may determine to be necessary or advisable. In the event that, at the time of issuance of the Shares to you, the Shares have not been registered or otherwise qualified as may be required under applicable securities laws, you shall, prior to the issuance of the Shares: (i) represent to the Company in form satisfactory to counsel for the Company, that you are acquiring the Shares for your own account and not with a view to the resale or distribution thereof, and (ii) agree that none of the Shares issued to you pursuant to exercise of the Option provided hereby may be sold, transferred or otherwise disposed of unless: (a) the Shares to be sold, transferred or otherwise disposed of will be registered or qualified under applicable securities laws at the time of such sale, transfer or other disposition and the Company has received an opinion of counsel satisfactory to it that such registration or qualification is effective; or (b) the Company shall have received an opinion of counsel or other information and representations, satisfactory to it, to the effect that such registration or qualification is not required. You shall also consent to execute any market standoff or lock-up agreement as requested by the Company.

6. ***No Right of Continued Employment***

. Nothing contained in the Plan or this Agreement shall restrict the right of the Company and/or its affiliates to terminate your employment or service. Any termination of your employment or service, regardless of the reason therefor, shall have the consequences provided for in the Plan and this Agreement with respect to your rights in respect of the Option.

7. ***Amendment***

. Except for limited circumstances as provided for in the Plan, this Agreement may be amended, in whole or in part and in any manner not inconsistent with the provisions of the Plan, at any time and from time to time, by written agreement between the Company and you.

8. ***Notice***

. Any notice to be given to the Company shall be in writing and either hand delivered or mailed to the office of the President of the Company. If mailed, it shall be addressed to the Company at its principal executive office, or at such other address as the Company may hereafter designate by written notice to you. Any notice given to you shall be addressed to you at your address as reflected in the personnel records of the Company, or at such other address as you may hereafter designate by written notice to the Company. Notice shall be deemed to have been duly delivered when hand delivered or, if mailed, on the fifth day after such notice is postmarked.

9. ***Transferability.*** The Option is not transferable or assignable other than by will or by the laws of descent and distribution. Any other attempt to transfer the Option, whether voluntary or involuntary, by operation of law or otherwise, will be ineffective. During your lifetime, the Option is exercisable only by you. Subject to the foregoing and the terms of the Plan, the terms and conditions of the Agreement will be binding upon your executors, administrators and heirs.

10. ***Company Policies.*** In consideration for the grant of the Option, you agree to be subject to all policies of the Company regarding clawback, securities trading and hedging or pledging of securities, as in effect from time to time.

11. ***Entire Agreement.*** The Grant Schedule and this Agreement, together with the Plan, represents the entire agreement between the parties with respect to the Option and supersedes any prior agreement, written or otherwise, relating to the Option.

[signature page follows]

The undersigned hereby acknowledges the award of the Option on behalf of the Company.

RECRO PHARMA, INC.

By: _____
Name: J. David Enloe, Jr.
Title: Chief Executive Officer
Date:

In order to indicate your acceptance of the Option evidenced by this Agreement and the Grant Schedule, subject to the restrictions and upon the terms and conditions set forth herein and in the Plan, please execute and immediately return to the Company the enclosed duplicate original of this Agreement.

ACCEPTED AND AGREED,
Intending to be legally bound:

Date:

Grant Schedule

Recipient's Name:

Grant Date:

Option Price:

Total Number of Shares Subject to the Option:

Type of Option: Non-Qualified Stock Option

Schedule of Vesting Dates:

Vesting Date	Number of Shares Then Vesting

Exhibit 10.27

Award Agreement for
Restricted Stock Units under the Recro Pharma, Inc.
Amended and Restated Equity Incentive Plan

THIS AWARD AGREEMENT FOR RESTRICTED STOCK UNITS (this "Agreement") is made by Recro Pharma, Inc. (the "Company") to the participant named on the grant schedule attached hereto (the "Grantee"), dated as of the date set forth on the grant schedule attached hereto (the "Grant Date").

RECITALS

WHEREAS, the Company desires to award Restricted Stock Units to the Grantee under the Recro Pharma, Inc. Amended and Restated Equity Incentive Plan (the "Plan"), pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Grant Schedule. Certain terms of the grant of Restricted Stock Units are set forth on the grant schedule (the "Grant Schedule") that is attached to, and is a part of, this Agreement.

2. Grant of Restricted Stock Units. As of the Grant Date, pursuant to the Plan, the Company hereby awards to the Grantee the number of Restricted Stock Units set forth on the Grant Schedule (the "Award"), subject to the restrictions and on the terms and conditions set forth in this Agreement and the Plan. The terms of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein. Capitalized terms used but not defined herein will have the same meaning as defined in the Plan.

3. Grant Date. The Grant Date of the Restricted Stock Units is set forth on the Grant Schedule.

4. Vesting. Subject to the further provisions of this Agreement, the Restricted Stock Units will vest as set forth on the Grant Schedule (each date on which Restricted Stock Units vest being referred to as a "Vesting Date"). Notwithstanding Section 8(a)(ii) of the Plan, no vesting of this Award will occur in connection with the Grantee's Retirement.

5. Transferability. The Restricted Stock Units are not transferable or assignable otherwise than by will or by the laws of descent and distribution. Any attempt to transfer Restricted Stock Units, whether by transfer, pledge, hypothecation or otherwise and whether voluntary or involuntary, by operation of law or otherwise, will not vest the transferee with any interest or right in or with respect to such Restricted Stock Units.

6. Termination of Employment or Service. In the event of the Grantee's termination of service with the Company and its Affiliates, all then unvested Restricted Stock Units (determined after giving effect to any accelerated vesting occurring in connection with such termination under the terms of the Grant Schedule, if any) will be forfeited.

7. Issuance of Shares.

a. Within thirty (30) days following each Vesting Date (including any accelerated vesting date provided in the Grant Schedule), the Company shall issue to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, a number of shares of Common Stock equal to the number of Restricted Stock Units granted hereunder that have vested as of such date. Any shares of Common Stock issued to the Grantee hereunder shall be fully paid and non-assessable.

b. The Grantee will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of Restricted Stock Units, until shares of Common Stock are issued in settlement of such Restricted Stock Units pursuant to Section 7.a hereof. Upon the issuance of a stock certificate or the making

of an appropriate book entry on the books of the transfer agent, the Grantee will haveall of the rights of a stockholder.

c. In consideration for the grant of this Award, the Grantee agrees to be subject to any policies of the Company and its Affiliates regarding clawbacks, securities trading and hedging or pledging of securities that may be in effect from time to time.

8. Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party hereto upon any breach or default of any party under this Agreement, will impair any such right, power or remedy of such party, nor will it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of any similar breach or default thereafter occurring, nor will any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in a writing signed by such party and will be effective only to the extent specifically set forth in such writing.

9. Withholding. In accordance with Section 15 of the Plan, the Company reserves the right to (i) withhold, in accordance with any applicable laws, from any consideration payable or property transferable to Grantee, or (ii) require the Grantee to remit to the Company an amount sufficient to satisfy, any taxes required to be withheld by federal, state or local law as a result of the grant or vesting of this Award or other disposition of the shares.

10. Right of Discharge Preserved. The grant of Restricted Stock Units hereunder will not confer upon the Grantee any right to continue in service with the Company or any of its subsidiaries or Affiliates.

11. The Plan. By accepting this Award, the Grantee acknowledges that the Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and accepts the Restricted Stock Units subject to all of the terms and provisions of the Plan, as amended from time to time. Pursuant to the Plan, the Board or its committee is authorized to interpret the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. By accepting this Award, the Grantee acknowledges and agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or its committee upon any questions arising under the Plan.

12. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the application of the principles of conflicts of laws.

[signature page follows]

The Award is made by the Company as of the date stated in the introductory paragraph.

RECRO PHARMA, INC.

By:

Name: J. David Enloe, Jr.
Title: Chief Executive Officer
Date:

In order to indicate your acceptance of this award of Restricted Stock Units subject to the restrictions and upon the terms and conditions set forth above, in the Agreement and in the Plan, please execute and immediately return to the Company the enclosed duplicate original of this Grant Schedule and the Agreement.

ACCEPTED AND AGREED,
Intending to be legally bound:

Date:

Grant Schedule

Grantee's Name:

Grant Date:

Number of Restricted Stock Units Granted:

Schedule of Vesting Dates:

Vesting Date	Number of Restricted Stock Units Vesting

Exhibit 10.28

Award Agreement for
Restricted Stock Units under the Recro Pharma, Inc.
2018 Amended and Restated Equity Incentive Plan

THIS AWARD AGREEMENT FOR RESTRICTED STOCK UNITS (this "Agreement") is made by Recro Pharma, Inc. (the "Company") to the participant named on the grant schedule attached hereto (the "Grantee"), dated as of the date set forth on the grant schedule attached hereto (the "Grant Date").

RECITALS

WHEREAS, the Company desires to award Restricted Stock Units to the Grantee under the Recro Pharma, Inc. 2018 Amended and Restated Equity Incentive Plan (the "Plan"), pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Grant Schedule. Certain terms of the grant of Restricted Stock Units are set forth on the grant schedule (the "Grant Schedule") that is attached to, and is a part of, this Agreement.

2. Grant of Restricted Stock Units. As of the Grant Date, pursuant to the Plan, the Company hereby awards to the Grantee the target number of Restricted Stock Units set forth on the Grant Schedule (the "Award"), subject to the restrictions and on the terms and conditions set forth in this Agreement and the Plan. The terms of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein. Capitalized terms used but not defined herein, including the Grant Schedule, will have the same meaning as defined in the Plan.

3. Grant Date. The Grant Date of the Restricted Stock Units is set forth on the Grant Schedule.

4. Performance Goals. The number of Restricted Stock Units earned hereunder will vary between zero and the maximum percentage of the target number of Restricted Stock Units set forth on the Grant Schedule. The determination of the actual number of Restricted Stock Units earned will be based on actual performance during the performance period indicated on the Grant Schedule, relative to the performance goals set forth on the Grant Schedule. Any Restricted Units that have not been earned as of the completion of the applicable performance period will be forfeited at that time.

5. Vesting.

a. Any earned Restricted Stock Units will vest and become payable only if the Grantee remains in continuous service with the Company through the date set forth on the Grant Schedule (the "Vesting Date"). For purposes of this Agreement, service with the Company will include service with an Affiliate (for only so long as such entity remains an Affiliate).

b. Notwithstanding the foregoing and Section 8(a)(ii) of the Plan, if the Grantee's service ceases due to his or her death or Disability, the service requirement described in Section 4(a) above will be waived, this Award will remain outstanding and any Restricted Stock Units earned upon conclusion of the applicable performance period will be deemed immediately vested.

c. Notwithstanding Section 8(a)(ii) of the Plan, no vesting of this Award will occur in connection with the Grantee's Retirement.

6. Transferability. The Restricted Stock Units are not transferable or assignable, other than by will or by the laws of descent and distribution. Any attempt to transfer Restricted Stock Units, whether by transfer, pledge, hypothecation or otherwise and whether voluntary or involuntary, by operation of law or otherwise, will not vest the transferee with any interest or right in or with respect to such Restricted Stock Units.

7. Termination of Employment. Except as otherwise provided in Section 4(b) above, upon cessation of the Grantee's service with the Company for any reason, any Restricted Stock Units that are unvested as of the date of such cessation (even if otherwise earned) will then be immediately and automatically forfeited.

8. Issuance of Shares.

a. Within (30) days following the Vesting Date (in the case of Restricted Stock Units vesting under Section 4(a)) or within 2½ months following the end of the applicable performance period (in the case of Restricted Stock Units vesting under Section 4(b)), the Company shall issue to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, a number of shares of Common Stock equal to the number of earned Restricted Stock Units that have vested. Notwithstanding the foregoing, to the extent provided in Prop. Treas. Reg. § 1.409A-1(b)(4)(ii) or any successor provision, the Company may delay settlement of Restricted Stock Units if it reasonably determines that such settlement will violate federal securities laws or any other applicable law. Any shares of Common Stock issued to the Grantee hereunder shall be fully paid and non-assessable.

b. The Company may require as a condition of the issuance of shares pursuant to Section 8(a) hereof that the Grantee remit to the Company an amount sufficient in the opinion of the Company to satisfy any federal, state and other governmental tax withholding requirements related to the issuance of such shares. The Board, in its sole discretion, may permit the Grantee to satisfy such obligation by delivering shares of Common Stock or by directing the Company to withhold from delivery shares of Common Stock, in either case valued at their Fair Market Value on the applicable issuance date, with fractional shares being settled in cash.

c. The Grantee will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of Restricted Stock Units, until shares of Common Stock are issued in settlement of such Restricted Stock Units pursuant to Section 8(a) hereof. Upon the issuance of a stock certificate or the making of an appropriate book entry on the books of the transfer agent, the Grantee will have all of the rights of a stockholder.

d. With respect to any grant of Restricted Stock Units that vests in whole or in part based on the Company's achievement of financial or operating results, if it is determined by the Board that gross negligence, intentional misconduct or fraud by Grantee caused or partially caused the Company to restate all or a portion of its financial statements, the Board shall, to the extent permitted by law, require repayment of shares delivered pursuant to the vesting of the Restricted Stock Units, and/or effect the cancellation of unvested Restricted Stock Units, if (i) the vesting of the Award was calculated based upon, or contingent on, the achievement of financial or operating results that were the subject of or affected by the restatement, and (ii) the extent of vesting of the Award would have been less had the financial statements been correct. The required repayment or cancellation shall be such as will put the Grantee in the same position relative to vesting of the Award as the Grantee would have been in had the financial statements been correct.

9. Securities Matters. The Company shall be under no obligation to effect the registration pursuant to the Securities Act of 1933, as amended (the "1933 Act") of any interests in the Plan or any shares to be issued thereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued any shares, whether by means of stock certificates or appropriate book entries, unless and until the Company is advised by its counsel that the issuance of such shares is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which Common Stock is traded. The Board may require, as a condition of the issuance of shares pursuant to the terms hereof, that the recipient of such shares make such covenants, agreements and representations, and that any certificates bear such legends and any book entries be subject to such electronic coding or stop order, as the Board, in its sole discretion, deems necessary or desirable. The Grantee specifically understands and agrees that shares of Common Stock, if and when issued, may be "restricted securities," as that term is defined in Rule 144 under the 1933 Act and, accordingly, the Grantee may be required to hold the shares indefinitely unless they are registered under the 1933 Act or an exemption from such registration is available.

10. Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party hereto upon any breach or default of any party under this Agreement, will impair any such right, power or remedy of such party, nor will it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of any similar breach or default thereafter occurring, nor will any waiver of any single breach or default be

deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in a writing signed by such party and will be effective only to the extent specifically set forth in such writing.

11. Tax Treatment; Withholding.

a. This Award is intended to be exempt from the requirements of Section 409A of the Code and should be interpreted accordingly. Nonetheless, the Company does not guaranty the tax treatment of this Award.

b. The Company reserves the right to withhold, in accordance with any applicable laws, from any consideration payable or property transferable to Grantee any taxes required to be withheld by federal, state or local law as a result of the grant, vesting or settlement of this Award.

12. Right of Discharge Preserved. The grant of Restricted Stock Units hereunder will not confer upon the Grantee any right to continue in service with the Company or any of its subsidiaries or Affiliates.

13. The Plan. By accepting this Award, the Grantee acknowledges that the Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and accepts the Restricted Stock Units subject to all of the terms and provisions of the Plan. Pursuant to the Plan, the Board or its committee is authorized to interpret the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. By accepting this Award, the Grantee acknowledges and agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or its committee upon any questions arising under the Plan.

14. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter this Agreement) shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the application of the principles of conflicts of laws.

15. Company Policies. In consideration for the grant of this Award, the Grantee agrees to be subject to all policies of the Company regarding clawback, securities trading and hedging or pledging of securities, as in effect from time to time.

16. Entire Agreement. The Grant Schedule and this Agreement, together with the Plan, represents the entire agreement between the parties with respect to this Award and supersedes any prior agreement, written or otherwise, relating to this Award.

[signature page follows]

The Award is made by the Company as of the Grant Date.

RECRO PHARMA, INC.

By:

Name: J. David Enloe, Jr.
Title: Chief Executive Officer
Date:

In order to indicate your acceptance of this award of Restricted Stock Units subject to the restrictions and upon the terms and conditions set forth above, in the Agreement and in the Plan, please execute and immediately return to the Company the enclosed duplicate original of this Grant Schedule and the Agreement.

ACCEPTED AND AGREED,
Intending to be legally bound:

Date:

Grant Schedule

Grantee's Name:

Grant Date:

Target Number of Restricted Stock Units:

Vesting Date:

Performance Period:

Performance Goal and Scale:

The measurement of performance will be made in the sole discretion of the Board. The Board may, in its sole discretion, adjust any performance goal to reflect the effects of changes in accounting principles, corporate transactions or other similar events or transactions.

Effect of Change of Control:

Exhibit 21.1

LIST OF SUBSIDIARIES

Subsidiary	Ownership percentage	Jurisdiction of incorporation or organization
Recro Gainesville LLC	100 %	Massachusetts
Recro Gainesville Development LLC	100 %	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Recro Pharma, Inc.:

We consent to the incorporation by reference in the Registration Statements (Nos. 333-236875, 333-229737, 333-229736, 333-224870, 333-223437, 333-223436, 333-216581, 333-216579, 333-208750, 333-208749, 333-206309, and 333-194730) on Form S-8, (No. 333-229734) on Form S-3, and (No. 333-201841) on Form S-1 of Recro Pharma, Inc. of our report dated February 26, 2021, with respect to the consolidated balance sheets of Recro Pharma, Inc. as of December 31, 2020 and 2019, the related consolidated statements of operations, shareholders' equity or deficit, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Recro Pharma, Inc.

Our report on the consolidated financial statements refers to a change in accounting principle for leases due to the adoption of a new accounting standard.

/s/ KPMG LLP

Philadelphia, Pennsylvania
February 26, 2021

Exhibit 31.1

CERTIFICATION

I, J. David Enloe, Jr., certify that:

1. I have reviewed this Annual Report on Form 10-K of Recro Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: February 26, 2021

/s/ J. David Enloe, Jr.
J. David Enloe, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Ryan D. Lake, certify that:

1. I have reviewed this Annual Report on Form 10-K of Recro Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: February 26, 2021

/s/ Ryan D. Lake
Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report of Recro Pharma, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: February 26, 2021

/s/ J. David Enloe, Jr.
J. David Enloe, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Ryan D. Lake
Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)