UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

For the transition period from to

Commission file number: **001-33137**

EMERGENT BIOSOLUTIONS INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**14-1902018**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
400 Professional Drive, Gaithersburg , Maryland	**20879**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (240) 631-3200
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, $0.001 par value per share	**New York Stock Exchange**

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 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 Rule 405 of Regulation S-T 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 definitions of "large accelerated filer," "accelerated filer," "non-accelerated filer", "smaller reporting company" and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check on):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2018 was approximately $2.1 billion based on the price at which the registrant's common stock was last sold on that date as reported on the New York Stock Exchange.

As of February 15, 2019, the registrant had 51.2 million shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2019 annual meeting of stockholders scheduled to be held in May 2019, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year ended December 31, 2018, are incorporated by reference into Part II, Item 5. and Part III of this annual report on Form 10-K. With the exception of the portions of the registrant's definitive proxy statement for its 2019 annual meeting of stockholders that are expressly incorporated by reference into this annual report on Form 10-K, such proxy statement shall not be deemed filed as part of this annual report on Form 10-K.

EMERGENT BIOSOLUTIONS INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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NOTE REGARDING COMPANY REFERENCES

References in this report to “Emergent,” the “Company,” “we,” “us,” and “our” refer to Emergent BioSolutions Inc. and its consolidated subsidiaries.

NOTE REGARDING TRADENAMES

BioThrax® (Anthrax Vaccine Adsorbed), RSDL® (Reactive Skin Decontamination Lotion Kit), BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], Anthrasil® (Anthrax Immune Globulin Intravenous [human]), NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), VIGIV [Vaccinia Immune Globulin Intravenous (Human)], Trobigard™ (atropine sulfate, obidoxime chloride), ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live), Vivotif® (Typhoid Vaccine Live Oral Ty21a), Vaxchora® (Cholera Vaccine, Live, Oral), NARCAN® (naloxone HCl) Nasal Spray and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and the documents we incorporate by reference include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding the future earnings and performance of Emergent BioSolutions Inc. or any of our businesses, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. We generally identify forward-looking statements by using words like "will," "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements, including, among others:

- § appropriations for the procurement of BioThrax® (Anthrax Vaccine Adsorbed) and our other products addressing public health threats;
- § our ability to perform under our contracts with the U.S. government related to BioThrax, our NuThrax™ product candidate, and our other public health threat products, including the timing of and specifications relating to deliveries;
- § our ability to obtain Emergency Use Authorization pre-approval for NuThrax (anthrax vaccine adsorbed with CPG 7909 adjuvant) from the U.S. Food and Drug Administration, or FDA;
- § the availability of funding for our U.S. government grants and contracts;
- § our ability to secure follow-on procurement contracts for our public health threat products that are under procurement contracts that have expired or will be expiring;
- § our ability and the ability of our collaborators to protect our intellectual property rights;
- § our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- § our ability to successfully integrate and realize the benefits of our acquisitions of PaxVax Holding Company Ltd. and Adapt Pharma Limited, both of which were acquired in October 2018;
- § our ability to successfully identify and respond to new development contracts with the U.S. government, as well as successfully maintain, through achievement of development milestones, current development contracts with the U.S. government;
- § our ability and the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- § the results of regulatory inspections;
- § the operating and financial restrictions placed on us and our subsidiaries under our senior secured credit facilities;
- § our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- § the procurement of products by U.S. government entities under regulatory exemptions prior to approval by the FDA and corresponding procurement by government entities outside of the United States under regulatory exemptions prior to approval by the corresponding regulatory authorities in the applicable country;
- § the success of our commercialization, marketing and manufacturing capabilities and strategy; and
- § the accuracy of our estimates regarding future revenues, expenses, capital requirements and needs for additional financing.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. New factors emerge from time to time and it is not possible for management to predict all such factors, nor can it assess the impact of any such factor on the business or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement. You should consider this cautionary statement, the risk factors identified in the section entitled "Risk Factors" in this annual report on Form 10-K and the risk factors identified in our periodic reports filed with the Securities and Exchange Commission when evaluating our forward-looking statements.

PART I
ITEM 1. BUSINESS

OVERVIEW

Emergent BioSolutions Inc. is a global life sciences company focused on providing to civilian and military populations a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring public health threats ("PHTs," each a "PHT"). We were incorporated in the State of Michigan in May 1998 and subsequently reorganized as a Delaware corporation in June 2004.

We are focused on the following four distinct PHT categories: Chemical, Biological, Radiological, Nuclear and Explosives ("CBRNE"); emerging infectious diseases ("EID"); travelers' diseases; and opioids. We have a product portfolio of eleven products (vaccines, antibody therapeutics, and drug-device combination products) that generate a majority of our revenue. We also have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates (vaccines, antibody therapeutics, and drug-device combination products). Finally, we also have a fully-integrated portfolio of contract development and manufacturing services. The U.S. government (the "USG") is the largest purchaser of our products and provides us with substantial funding for the development of a number of our product candidates. We continue to pursue acquiring and developing products and solutions that provide an opportunity to serve both government customers and commercial (non-government) customers ("Dual Market").

STRATEGY

Our strategy is centered on our core business of addressing PHTs. This strategy contemplates that we:

- Continue to leverage and expand our leadership position in the PHT market, now further expanded to encompass the opioid and travelers' markets as well as the CBRNE and EID markets;
- Grow through the acquisition of products and businesses, particularly those that are revenue-generating and accretive;
- Develop and manufacture innovative products and solutions, particularly with funding from governments and non-governmental organizations to defray research and development costs;
- Focus on globalization and related international commercial capabilities; and
- Diversify our product mix to include products that have Dual Market potential.

In executing on our strategy, we are leveraging our core competencies. These competencies include:

- Unique and valuable commercial and government solutions for PHTs through formation of public-private partnerships;
- Quality manufacturing across a spectrum of specialized and complex manufacturing processes, using multiple platform technologies;
- Specialized government relations and contracting operations to support our government contracting business;
- Successful completion of business and product acquisitions; and
- Financial discipline driven by a prudent capital allocation strategy focused on generating positive returns on invested capital.

GROWTH THROUGH ACQUISITIONS AND COLLABORATIONS

We have a track record of growth through the acquisition of revenue-generating and accretive products and businesses. Our goal is to continue our expansion through targeted acquisitions of (1) government-procured products; (2) Dual-Market product opportunities, which are products that have both government and non-government / commercial market potential; and (3) products that are purely commercial in nature, but would leverage our core competencies in a unique way. Below is a summary of our significant acquisitions, transactions and collaborations.

Adapt Pharma Limited

On October 15, 2018, we completed the acquisition of Adapt Pharma Limited ("Adapt"), and its NARCAN® (naloxone HCl) Nasal Spray marketed product, the first and only needle-free formulation of naloxone approved by the Food and Drug Administration ("FDA"), and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. This acquisition includes the NARCAN® Nasal Spray marketed product and a development pipeline of new treatment and delivery options to address opioid overdose, and approximately 50 employees, located in the U.S., Canada, and Ireland, including those responsible for supply chain management, research and development, government affairs, and commercial operations.

We paid approximately $581.5 million in cash at the closing (inclusive of closing adjustments) and issued 733,309 shares of Common Stock, based on the volume-weighted average price per share of the Common Stock as reported on the New York Stock Exchange for the ten-trading day period ending two days before closing, or $65.28 per share (an aggregate total of $47.9 million, inclusive of adjustments). The remaining consideration payable for the acquisition consists of up to $100 million in cash based on the achievement of certain sales milestones through 2022. The Company funded the cash portion of the payments made at closing using a combination of cash-on-hand and borrowings under its Amended Credit Agreement, as described in the *Long-term debt* section below.

PaxVax Holding Company Ltd.

On October 4, 2018, we completed the acquisition of PaxVax Holding Company Ltd. ("PaxVax"), a company focused on developing, manufacturing, and commercializing specialty vaccines that protect against existing and emerging infectious diseases. This acquisition includes Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever, Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera, an adenovirus 4/7 vaccine candidate being developed for military personnel under contract with the U.S. Department of Defense ("DoD") and additional clinical-stage vaccine candidates targeting chikungunya and other emerging infectious diseases, European-based current good manufacturing practices ("cGMP") biologics manufacturing facilities, and approximately 250 employees including those in research and development, manufacturing, and commercial operations with a specialty vaccines salesforce in the U.S. and in select European countries.

At the closing, we paid a cash purchase price of $273.1 million (inclusive of closing adjustments), using a combination of cash-on-hand and borrowings under our senior secured credit agreement.

ACAM2000

In October 2017, we completed the acquisition of the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) business of Sanofi Pasteur Biologics, LLC. This acquisition included ACAM2000, the only smallpox vaccine licensed by the FDA, a licensed, live-viral manufacturing facility and office and warehouse space, both in Canton, Massachusetts (for which we received FDA manufacturing approval for the transfer of the upstream portion of the manufacturing process of ACAM2000 in November 2017), and a live-viral fill/finish facility in Rockville, Maryland. With this acquisition, we also acquired a 10-year contract with the Centers for Disease Control and Prevention ("CDC"), which expired in March 2018. This contract was originally valued at up to $425 million, and upon acquisition had a remaining value at acquisition of up to approximately $160 million, reflecting the value of doses of ACAM2000 remaining to be delivered to the U.S. Strategic National Stockpile ("SNS"). As of December 31, 2018, there remains a portion of doses still to be delivered to the SNS under the current BARDA procurement contract. We expect to complete deliveries of such doses in 2019. We are negotiating a new multi-year contract with the Assistant Secretary for Preparedness and Response ("ASPR") to deliver additional doses into the SNS.

Total consideration for this acquisition was $125 million. At closing, we paid $117.5 million in cash. The agreement also included an additional cash milestone payment of $7.5 million based upon FDA approval of the Canton facility for the manufacturing of ACAM2000. This regulatory milestone was achieved based on such approval in November 2017 and paid in cash in the fourth quarter of 2017.

raxibacumab

In October 2017, we completed the acquisition from Human Genome Sciences, Inc. and GlaxoSmithKline LLC, collectively GSK, of raxibacumab, the first fully-human monoclonal antibody product licensed by the FDA for the treatment and prophylaxis of inhalational anthrax. Total consideration for this acquisition was up to $96 million. At closing, we paid $76 million in cash. The agreement also included up to $20 million in future cash payments tied to product sales and manufacturing-related milestones. As of December 31, 2018, the milestones had not yet been achieved. With the acquisition, we assumed responsibility for a multi-year contract with the Biomedical Advanced Research and Development Authority ("BARDA") with a remaining value at acquisition of up to approximately $130 million, to supply raxibacumab to the SNS through November 2019. We are currently in the process of pursuing FDA licensure for the transfer of bulk manufacturing of raxibacumab to our Bayview facility and the fill/finish process to our Camden facility, and under the terms of the acquisition agreements we will purchase product from GSK to enable completion of deliveries to the SNS under the current BARDA procurement contract.

Spin-Off of Biosciences Business

In August 2016, we completed a tax-free spin-off of our former biosciences business into a separate, stand-alone publicly-traded company, Aptevo Therapeutics Inc. ("Aptevo"). As part of the spin-off transaction, the assets that were a part of our former biosciences business segment were transferred to Aptevo. These assets included our former biosciences commercial products IXINITY [coagulation factor IX (recombinant)], WinRho® SDF [(Rho(D) Immune Globulin Intravenous (Human)], HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)] and VARIZIG® [Varicella Zoster Immune Globulin (Human)], as well as our former oncology and hematology therapeutics development assets and platforms.

Cangene Corporation

In February 2014, we acquired Cangene Corporation, which included the following products: BAT® for the treatment of botulism; Anthrasil for the treatment of anthrax infection; and VIGIV for the treatment of adverse reactions to vaccinia virus vaccinations. The acquisition also included a hyperimmune technology platform as part of a manufacturing site in Winnipeg, Manitoba, Canada (our Winnipeg site), and which is used to manufacture the BAT, Anthrasil and VIGIV products. We also acquired Cangene's fill/finish contract manufacturing services business in Baltimore, Maryland (our Camden facility), including agreements with customers to fill/finish a number of commercial and clinical-stage products worldwide.

Other Acquisitions and Collaborations

In recent years, we have also entered into the following other transactions.

- In August 2018, our collaboration with the Coalition for Epidemic Preparedness Innovations ("CEPI") and Profectus BioSciences, Inc. ("Profectus"), under which we intend to advance the development and manufacture of a vaccine against the Lassa virus;
- In November 2017, our agreement with Profectus to have the option to license multiple vector vaccine product candidates, including those for Nipah, and viral hemorrhagic fevers caused by Ebola, Marburg and Lassa viruses;
- In July 2017, our collaboration with Southwest Research Institute, an independent, nonprofit applied research and development organization headquartered in San Antonio, Texas, under which we are developing an intra-nasal spray device for the treatment of known or suspected acute cyanide poisoning; and
- In December 2015, our acquisition of Unither Virology LLC, which held a broad family of iminosugar small molecules that have activity against a variety of enveloped viruses.

OUR BUSINESS UNITS

We are organized into four business units: Vaccines and Anti-Infectives; Devices; Antibody Therapeutics; and Contract Development and Manufacturing.

Vaccines and Anti-Infectives

Products

Our Vaccines and Anti-Infectives business unit contains a portfolio of specialty vaccines and unique anti-infectives that address existing and emerging PHTs. The current portfolio consists of the following products.

VACCINES AND ANTI-INFECTIVES UNIT		
Product	**Indication(s)**	**Regulatory Approvals**
BioThrax® (Anthrax Vaccine Adsorbed)	GUP - General use prophylaxis of anthrax disease; and PEP - Post-exposure prophylaxis of anthrax disease in combination with appropriate antibacterial drugs.	United States, Germany, Singapore, UK, Germany, Netherlands, France, Poland, Italy and Canada.
ACAM2000® (Smallpox (Vaccinia) Vaccine, Live)	Vaccination for active immunization against smallpox disease for persons determined to be at high risk for smallpox.	United States, Australia, Singapore
Vaxchora® (Cholera Vaccine Live Oral)	Oral vaccine for the prevention of cholera.	United States
Vivotif® (Typhoid Vaccine Live Oral Ty21a)	Oral vaccine for the prevention of typhoid fever.	United States, Canada, Australia, New Zealand, Singapore, South Korea, Hong Kong, Malaysia, UK, France, Italy, Portugal, Spain,

		Switzerland, Belgium, Luxembourg, The Netherlands, Germany, Austria, Norway, Denmark, Finland, Sweden, The Czech Republic, Slovakia

BioThrax® (Anthrax Vaccine Adsorbed). BioThrax is the only vaccine licensed by the FDA for the general use prophylaxis ("GUP"), of anthrax disease. In April 2014, the FDA granted orphan drug designation to BioThrax for the post-exposure prophylaxis ("PEP"), indication, (please see "Regulation – Marketing Approval – Biologics, Drugs and Vaccines– Orphan Drugs"), giving it market exclusivity in the United States until November 2022. In November 2015, the FDA approved our supplemental Biologics License Application ("BLA"), to expand the BioThrax label to include the PEP indication for BioThrax administered in combination with antimicrobial therapy. Anthrax is a potentially fatal disease caused by the spore forming bacterium, Bacillus anthracis. Inhalational anthrax is the most lethal form of anthrax. Death due to inhalational anthrax infection often occurs within 24-36 hours of the onset of advanced respiratory complications. In the U.S., BioThrax is administered in a GUP setting by intramuscular injection in a three-dose primary series over an initial six-month period. The vaccine is protective after completion of this three-dose primary series. After the primary series, two additional doses are given one each at 12 and 18 months, with booster doses annually thereafter. BioThrax is administered in a PEP setting in conjunction with recommended antibacterial drugs following suspected or confirmed *Bacillus anthracis* exposure. The vaccination schedule for PEP consists of three doses of BioThrax administered subcutaneously at 0, 2- and 4-weeks post-exposure combined with antimicrobial therapy. In December 2016, we signed a follow-on contract with the CDC, an agency within the U.S. Department of Health and Human Services ("HHS") for the supply of up to approximately 29.4 million doses of BioThrax for delivery into the SNS, over a five-year period ending in September 2021. The potential value of this contract is approximately $911 million, if all procurement options are exercised. In March 2017, we entered into an additional contract with BARDA, originally valued at up to $100 million, for the delivery of BioThrax to the SNS, over a two-year period of performance. We completed deliveries under this contract in 2017.

In August 2016, the FDA licensed Building 55, our large-scale manufacturing facility in Lansing, Michigan, for the manufacture of BioThrax. This facility has the potential to manufacture up to 20 to 25 million doses of BioThrax annually.

ACAM2000® (Smallpox (Vaccinia) Vaccine, Live). ACAM2000 is the only smallpox vaccine licensed by the FDA and is the primary smallpox vaccine designated for use in a bioterrorism emergency, with more than 230 million doses having been supplied to the SNS. ACAM2000 is also licensed in Australia and Singapore and is currently stockpiled both in the United States and internationally. Smallpox is a highly contagious disease caused by the variola virus, a member of the orthopox virus family. According to the CDC, it is one of the most devastating diseases with a mortality rate as high as 30%. ACAM2000 is administered by percutaneous route in one dose with a bifurcated needle using the multiple puncture method. The vaccine stimulates a person's immune system to develop antibodies and cells in the blood and elsewhere that can then help the body fight off a smallpox infection if exposure to smallpox occurs. Upon the closing of the ACAM2000 acquisition, we acquired a 10-year CDC contract, which expired in March 2018. The original contract, valued at up to $425 million, called for the delivery of ACAM2000 to the SNS and establishing U.S.-based manufacturing of ACAM2000, specifically the transfer of the upstream portion of the ACAM2000 production process from Austria to a U.S.-based manufacturing facility. This technology transfer was completed and approved by the FDA in November 2017 and we are continuing to make deliveries under the prior contract. At acquisition, there was $160 million of remaining value on the prior contract subject to the availability of government funding, and we expect to fulfill the remaining product deliveries to the SNS in the first half of 2019. We are negotiating a new multi-year contract with ASPR to deliver additional doses into the SNS.

Vaxchora®. (Cholera Vaccine Live Oral) Vaxchora is a live attenuated cholera vaccine for oral administration and the first vaccine approved by the FDA for the prevention of cholera infection. Cholera, a potentially life-threatening bacterial infection that occurs in the intestines and causes severe diarrhea and dehydration, has a low incidence in the U.S., but a high incidence in Africa, Southeast Asia, and other locations around the world. These areas draw travelers from the U.S., so cholera can occur in patients who return to the U.S. from visits to these regions. Vaxchora is indicated for active immunization against cholera caused by the bacterium *V. cholerae* serogroup O1. Vaxchora is approved for use in patients 18–64 years of age who are traveling to known cholera-infected areas.

Vivotif®. (Typhoid Vaccine Live Oral Ty21a) Vivotif is a live attenuated vaccine for oral administration to prevent typhoid fever. The vaccine contains the attenuated strain Salmonella typhi Ty21a (1,2). Typhoid fever is a potentially severe and occasionally life-threatening febrile illness caused by Salmonella enterica serotype Typhi (S Typhi), a bacterium that only lives in humans. It is usually acquired by consumption of water or food that has been contaminated by feces of an infected person. Typhoid fever is uncommon in North America and Europe. However, travelers from North America and Europe going to Asia, Africa, and Latin America have been particularly at risk. Even short-term travel to high-incidence areas is associated with risk for typhoid fever. In the U.S., Vivotif is indicated for immunization of adults and children greater than 6 years of age against disease caused by S Typhi.

Product Candidates

The chart below highlights our primary Vaccines and Anti-infectives product candidates.

Product Candidate	Partner	Platform	Threat Type
NuThrax™ *Next generation anthrax vaccine*	**HHS - BARDA**	**Vaccine**	**Biological**
CHIKUNGUNYA *Chikungunya VLP vaccine*	**--**	**Vaccine**	**EID**
ADENOVIRUS 4/7 *Live, attenuated vaccine*	**DoD - USAMRAA**	**Vaccine**	**EID**
rVSV-Lassa *Vaccine for prevention of Lassa fever*	**CEPI**	**Vaccine**	**EID**
rVSV-Marburg *Vaccine for prevention of Marburg hemorrhagic fever*	**--**	**Vaccine**	**Biological**
rVSV-Sudan *Vaccine for prevention of Sudan hemorrhagic fever*	**--**	**Vaccine**	**Biological**
rVSV-QUAD *Vaccine for prevention of hemorrhagic fever caused by infection with Lassa, Ebola, Sudan or Marburg virus*	**NIAID (to Profectus)**	**Vaccine**	**Biological**
rVSV-Ebola *Vaccine for prevention of Ebola hemorrhagic fever*	**--**	**Vaccine**	**Biological**

NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant). We are developing NuThrax, an anthrax vaccine product candidate based on BioThrax combined with CPG 7909, an adjuvant that we license from Pfizer Inc. We are developing NuThrax, in part with funding from the National Institute of Allergy and Infectious Diseases ("NIAID") and BARDA, to potentially elicit a more rapid onset of immune response using fewer doses than BioThrax while still providing protective immunity in patients. Using funds from our 2010 development contract with NIAID, in October 2014, we completed a Phase 2 safety, immunogenicity and dose ranging clinical trial of NuThrax in which all endpoints were successfully met, including requiring a two-dose regimen, versus the BioThrax three-dose regimen, which may shorten the recommended antibiotic (60-day) regimen for anthrax post-exposure prophylaxis. In September 2014, we also obtained additional funding through a five-year development contract with NIAID of up to $29 million to support the development of a dry formulation of NuThrax, including: assay development and non-clinical activities through the preparation of an Investigational New Drug ("IND") application to the FDA. The dry formulation of NuThrax is intended to increase stability of the vaccine candidate at ambient and higher temperatures, with the objective of eliminating the need for cold chain during shipping and storage. In March 2015, we signed a development contract with BARDA valued at $31 million to develop NuThrax for post-exposure prophylaxis of anthrax disease. In September 2016, we signed a combination development and procurement contract with BARDA for up to approximately $1.5 billion, including a five-year base period of performance valued initially at approximately

$200 million to develop NuThrax for post-exposure prophylaxis of anthrax disease and to deliver to the SNS an initial two million doses, subsequently modified to three million doses in March 2017, following Emergency Use Authorization ("EUA") pre-approval by the FDA. We applied for EUA in the fourth quarter of 2018 and, although there can be no assurances, we anticipate that the FDA could grant EUA designation to NuThrax as early as this year, triggering the initial three million dose delivery of NuThrax into the SNS in 2019. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax into the SNS, valued from approximately $255 million to up to $1.3 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at $48 million, which, if all were to be exercised in full, could increase the total contract value to approximately $1.5 billion. See "*Management's Discussion and Analysis of Financial Conditions and Results of Operations – Overview – Highlights* and Business Accomplishments for 2018" for additional details.

Chikungunya. We licensed the chikungunya virus ("CHKV"), a virus-like particle ("VLP"), vaccine product candidate from the Vaccine Research Center ("VRC") at the National Institutes of Health ("NIH"). VLPs for alphaviruses are comparable to the physical structure of the native virus, and contain repetitive, high density displays of viral surface proteins that present conformational viral epitopes that elicit strong B- and T-cell immune responses. Since VLPs cannot replicate, they provide a safer alternative to attenuated and inactivated vaccines throughout production and use and can be administered in unrestricted target populations. VRC has previously demonstrated in this product candidate both nonclinical and clinical (Phase 1) safety, immunogenicity and efficacy data. A key passive transfer study demonstrated that mice dosed with purified antibody from VLP-immunized NHPs were protected from an otherwise lethal CHKV infection. We established and scaled a CHKV cGMP production process at our facilities in San Diego, California. A Phase 1 trial demonstrated that the vaccine elicits anti-CHKV neutralizing antibody responses in humans significantly above the level believed to be protective in the passive transfer study. Two Phase 2 safety and immunogenicity trials are currently ongoing. The NIH has sponsored a Phase 2 trial at multiple endemic sites in the Caribbean. The study is a double-blind, placebo-controlled study with 200 subjects, which was initiated in 2016. The subjects are currently being followed for safety, immunogenicity and efficacy. As of August 2018, we have completed enrollment of the Phase 2 study. The primary objectives are to assess safety and anti-CHKV neutralizing antibody responses with different doses, different formulations and different dosing schedules. The study will also assess duration of neutralizing antibody responses induced by different formulations and schedules. Upcoming development activities include Phase 3 development, including process validation and manufacture, Phase 3 clinical studies in the U.S. and CHKV endemic areas, supportive nonclinical toxicity and efficacy studies, and a BLA submission. Collectively, these studies are intended to provide clinical and regulatory data for U.S. licensure and possible World Health Organization prequalification.

Adenovirus 4/7. In 2014, we formed a partnership with the DoD to modernize the production of the Adenovirus vaccine ("ADVV-MP"). An IND application for a new ADVV-MP was submitted to the FDA on January 30, 2017 and a Phase 1 study has been completed that demonstrates high seroconversion rates for Ad 7, indicating vaccine efficacy. Further development activities of the ADVV-MP will be dependent upon a continued partnership with the DoD and subject to government funding.

rVSV-VHF (vector vaccines for hemorrhagic fever). In November 2017, we entered into an agreement with Profectus to have the option to license multiple vector vaccine product candidates, including those for Nipah, and viral hemorrhagic fevers caused by Ebola, Marburg and Lassa viruses. In April 2018, we exercised our development license for rVSV-Marburg and rVSV-Quad vaccines. In October 2018, we exercised our development rights to rVSV-Lassa, rVSV-Ebola and rVSV-Sudan. The rVSV-Quad vaccine development is currently being funded by a contract award to Profectus from the NIAID under which we are performing manufacturing activities.

In August 2018, CEPI announced a collaboration with us and Profectus, under which the parties may receive up to $36 million to advance the development and manufacture of a vaccine against the Lassa virus. Lassa virus infection—a single-stranded RNA virus belonging to the family Arenaviridae—can cause the acute viral hemorrhagic illness known as Lassa fever. The virus is spread to humans via contact with food or household items that have been contaminated with urine or feces from *Mastomys* rats. Under the terms of the Framework Partnering Agreement for the collaboration among the three parties, Profectus will receive development funding from CEPI for advancing its Lassa virus vaccine. CEPI will provide $4.3 million to support the first phase of the project, with options to invest up to a total of $36 million over five years, including procurement of the vaccine for stockpiling purposes. We will provide technical and manufacturing support for the CEPI-funded program. Through our agreement executed with Profectus in October 2018, we have exercised the option to license and to assume control of development activities for the rVSV-Lassa vaccine from Profectus.

Below is a brief description of the primary rVSV-VHF candidates.

- ***rVSV-Lassa***, a recombinant vesicular stomatitis virus vectored vaccine for prevention of Lassa fever;
- ***rVSV-Marburg***, a recombinant vesicular stomatitis virus vectored vaccine for prevention of viral hemorrhagic fever caused by infection with Marburgvirus;
- ***rVSV-Ebola***, a recombinant vesicular stomatitis virus vectored vaccine for prevention of viral hemorrhagic fever caused by infection with *Zaire ebolaviruses*;
- ***rVSV-Sudan***, a recombinant vesicular stomatitis virus vectored vaccine for prevention of viral hemorrhagic fever caused by infection with Sudan Ebolavirus; and
- ***rVSV-QUAD***, a recombinant vesicular stomatitis virus vectored vaccine for prevention of hemorrhagic fever caused by infection with Lassa, Ebola, Marburg or Sudan virus infections.

Our Vaccines and Anti-Infectives business unit has other product candidates addressing PHTs, including influenza, anti-bacterials, and antivirals, among others.

Devices

Products

Our Devices business unit contains a broad portfolio of drug-device combination products that incorporate convergent technologies that enable both governments and patients (Dual Market) opportunities to address PHTs and challenging life-threatening conditions. The current portfolio consists of the following drug-device combination products.

DEVICES UNIT		
Product	**Indication(s)**	**Regulatory Approvals**
NARCAN® (naloxone HCl)Nasal Spray	Emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression	· United States · Canada
RSDL® (Reactive Skin Decontamination Lotion Kit)	Removal or neutralization of chemical warfare agents and T-2 toxin from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin.	· United States (510k) · Canada · Australia · European Union · Israel
Trobigard™ (atropine sulfate, obidoxime chloride	Auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride as a nerve agent countermeasure.	Trobigard is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to

		authorized government buyers for use outside the United States. This product is not distributed in the United States.

NARCAN® (naloxone HCl) Nasal Spray. NARCAN® (naloxone HCl) Nasal Spray is the first and only needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. The primary customers for NARCAN® Nasal Spray are state health departments, local law enforcement agencies, community-based organizations, substance abuse centers, federal agencies and consumers through physician directed or standing order prescriptions.

RSDL® (Reactive Skin Decontamination Lotion Kit). RSDL is the only medical device cleared by the FDA that is intended to remove or neutralize chemical warfare agents from the skin, including tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin. RSDL has also been cleared as a medical device by Health Canada, has a current European Conformity ("CE") mark under European Directives, and is licensed by the Israel Ministry of Health and by Australia's Therapeutics Goods Administration. To date, the principal customers for RSDL have been agencies of the USG, including the DoD and the National Guard. Our current contract with the DoD, awarded in September 2017 after the expiration of our initial DoD contract, is a five-year follow-on contract valued at up to approximately $171 million to supply RSDL for use by all branches of the U.S. military. In addition to the DoD and other USG agencies, beginning in 2017, we made RSDL available for the first time for purchase by civilians in the United States on Amazon.com. We have also sold RSDL to 35 foreign countries outside the United States since the device was cleared in 2003. We intend to continue our sales to USG agencies and the DoD and to identify new markets where RSDL can be promoted and sold under its current FDA clearance.

Trobigard™ (Atropine Sulfate/Obidoxime Chloride auto-injector). Trobigard auto-injector is designed to deliver atropine sulfate and obidoxime chloride for emergency treatment of organophosphate nerve agent or insecticide poisoning. In October 2017, we were awarded a contract, valued at up to approximately $25 million by the U.S. Department of State ("DoS"), to deliver our Trobigard product and training auto-injectors for emergency use outside of the United States. The contract consists of a one-year base period of performance with a six-month option period. Trobigard is not currently approved or cleared by the FDA or any similar regulatory body and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Product Candidates

Within our Devices business unit, we are leveraging our proprietary auto-injector platform to develop several investigational stage product candidates, including:

SIAN (stabilized isoamyl nitrite). In September 2017, we were awarded a contract by BARDA valued at approximately $63 million to develop an antidote intra-nasal spray device for the treatment of known or suspected acute cyanide poisoning. The single-use intranasal spray device is being developed to deliver a stabilized form of isoamyl nitrite ("SIAN") and is intended to be developed for use by first responders and medical personnel following a cyanide incident.

D4. In July 2017, we were awarded a contract by DoD valued at up to approximately $23 million to develop a multi-drug auto-injector for nerve agent antidote delivery (atropine and pralidoxime chloride), which we refer to as D4.

Development Candidates from Adapt Acquisition. We acquired from Adapt multiple constructs in various stages of development focused on new treatments and delivery options for opioid overdose response.

In addition, we are continuing to look at opportunities to expand our portfolio of auto-injector product candidates and, eventually, product line.

Antibody Therapeutics

Products

Our Antibody Therapeutics business unit contains a broad portfolio of specialty antibody-based therapeutics and prophylactics that address a broad range of existing and emerging PHTs. The current portfolio consists of the following products.

ANTIBODY THERAPEUTICS UNIT		
Product	**Indication(s)**	**Regulatory Approvals**
raxibacumab	Treatment and prophylaxis of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate.	United States
Anthrasil® [Anthrax Immune Globulin Intravenous (Human)]	Treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs.	United States, Canada
BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)]	Treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.	United States, Canada
VIGIV [Vaccinia Immune Globulin Intravenous (Human)]	Treatment of complications due to vaccinia vaccination, including: • Eczema vaccinatum; • Progressive vaccinia; • Severe generalized vaccinia; and • Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis).	United States, Canada

raxibacumab. raxibacumab is the first fully-human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax due to *bacillus anthracis*. It was licensed by the FDA in December 2012 and has orphan drug designation in the United States, giving it market exclusivity in the United States until December 2019. raxibacumab is indicated for the treatment of adult and pediatric patients with inhalational anthrax in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or not appropriate. raxibacumab has been supplied to the SNS since 2009 under contracts with BARDA. Upon the closing of our acquisition of raxibacumab from GSK, we assumed responsibility for a multi-year contract with BARDA, valued at up to approximately $130 million at acquisition, to supply the product to the SNS through November 2019. We intend to pursue negotiation of a follow-on contract with the USG to ensure the uninterrupted supply of this medical countermeasure ("MCM") to the SNS. Under the terms of our acquisition agreements, we intend to purchase product from GSK to enable completion of deliveries to the SNS under the existing BARDA procurement contract. We have initiated the process of the transfer of raxibacumab bulk manufacturing from GSK to our Bayview facility and fill/finish activities to our Camden facility.

Anthrasil® [Anthrax Immune Globulin Intravenous (Human)]. Anthrasil is the only polyclonal antibody therapeutic licensed by the FDA for the treatment of inhalational anthrax. Anthrasil is comprised of purified human polyclonal immune globulin G ("IgG") containing polyclonal antibodies directed to the anthrax toxins of *Bacillus anthracis*, the bacteria that causes anthrax disease, and is prepared using plasma collected from healthy, screened donors who have been immunized with our BioThrax vaccine. Anthrasil was licensed by the FDA in March 2015 for the treatment of suspected or documented inhalational anthrax in combination with appropriate antibacterial drugs. Simultaneous with FDA approval in 2015, Anthrasil also received orphan drug designation, resulting in market exclusivity in the United States until March 2022. To date, the principal customer for Anthrasil has been the USG, specifically HHS. Anthrasil is procured by BARDA for delivery into the SNS. We have two current contracts with BARDA: a development and procurement

contract that expires in April 2021 and a multiple award, indefinite delivery/indefinite quantity contract for the collection of anti-anthrax plasma, as well as the manufacture of such plasma into bulk drug substance and finished drug product and delivery of finished product into the SNS. BARDA issued a task order under this second contract for the collection of anti-anthrax plasma, which was completed in 2015. BARDA issued a second task order in 2018 under this contract to extend the plasma collection storage, and to include options for manufacturing and product delivery; these options are available to be exercised by BARDA through September 2023. In addition to domestic government sales, Anthrasil has been sold to several foreign governments. In December 2017, we were awarded a contract by the Canadian Department of National Defence, valued at approximately $8 million, to deliver Anthrasil to the Canadian government. This contract award follows the December 2017 approval of Anthrasil by Health Canada under the Extraordinary Use New Drug ("EUND") Regulations, which provide a regulatory pathway in Canada for products for which collecting clinical information for its intended use in humans is logistically or ethically not possible.

BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)]. BAT is the only heptavalent antibody therapeutic licensed by the FDA and Health Canada for the treatment of botulism. BAT is comprised of purified polyclonal equine immune globulins (antibodies) directed to the seven toxins (A through G) produced by *Clostridium botulinum*. BAT was licensed by the FDA in the United States in March 2013 for the treatment of suspected or documented exposure to botulinum neurotoxin A, B, C, D, E, F or G. It was also licensed in Canada in December of 2016 pursuant to Health Canada's EUND regulations. Simultaneous with FDA licensure in 2013, BAT also received orphan drug designation, resulting in market exclusivity in the United States until March 2020. BAT is the only heptavalent botulism antitoxin available in the United States or Canada for treating naturally occurring botulism in adults or pediatric patients. Botulinum toxin is a nerve toxin produced by the bacterium *Clostridium botulinum* that causes botulism, a serious paralytic illness. Naturally occurring cases are mainly seen in infants or in adults who have consumed improperly processed foods. Botulinum toxin can also be used as a bioterrorism agent and has been identified in the United States as one of the highest priority bioterrorism threats. To date, the principal customer for BAT has been the USG, specifically HHS. We are currently operating under a procurement contract with BARDA in support of the program; this contract also includes stability testing, post marketing commitments, and manufacturing. We signed a modification to our contract with BARDA to manufacture and store bulk drug substance for BAT in March 2017, valued at approximately $53 million with a five-year period of performance. This modification to the contract is intended to enable future filling and deliveries of final drug product to the SNS. In addition to domestic government sales, BAT continues to be sold internationally, with deliveries to over 15 foreign governments in 2018. For example, we have a 10-year contract, executed in 2012, to supply BAT to the Canadian Department of National Defense as well as the Public Health Agency of Canada and individual provincial health authorities.

VIGIV [Vaccinia Immune Globulin Intravenous (Human)]. VIGIV is the only polyclonal antibody therapeutic licensed by the FDA to address certain complications from smallpox vaccination. VIGIV is comprised of purified polyclonal human immune globulins (antibodies) directed to the vaccinia virus, the virus that is used in replicating virus vaccinations, such as ACAM2000, a product that is currently being procured and delivered into the SNS. VIGIV is prepared using plasma collected from healthy, screened donors who have been immunized with our ACAM2000 vaccine or previously immunized with the DryVax vaccine. Vaccinia is not the virus that causes smallpox, but it is similar enough to elicit a protective immune response when used as a smallpox vaccine. Individuals who are susceptible to vaccinia may develop an infection from ACAM2000 or other similar replicating virus vaccines, and these patients may benefit from treatment with VIGIV. VIGIV was licensed by the FDA in May 2005 and by Health Canada in May 2007 for counteracting certain complications that can be associated with smallpox vaccination. Although VIGIV has been sold to foreign governments, to date, the principal customer for VIGIV has been the USG, specifically HHS. We are operating under a contract for the supply of VIGIV through early 2019 and anticipate negotiating a follow-on contract for the continued supply of VIGIV into the SNS.

Product Candidates

The chart below highlights our primary Antibody Therapeutics product candidates:

Product Candidate	Target Indication
FLU-IGIV *Seasonal influenza therapeutic*	Treatment of serious Influenza A infection in hospitalized patients.
ZIKV-IG *Zika therapeutic*	Prophylaxis for Zika infections in at risk populations.

FLU-IGIV (NP025). We are utilizing our hyperimmune platform to develop NP025, a human polyclonal antibody therapeutic enriched with influenza antibodies for the treatment of serious illness caused by influenza A infection in hospitalized patients. Development of an influenza immune globulin product could address the significant public health burden for severe hospitalized influenza. In 2017, a Phase 2 study was initiated as a randomized, double-blind, placebo-controlled dose ranging study evaluating the safety, pharmacokinetics and clinical benefit of FLU-IGIV in a targeted hospitalized influenza patient population. This study is currently ongoing at multiple sites in North America with a target completion in 2019.

ZIKV-IG (NP024). ZIKV-IG is a sterile purified liquid immunoglobulin preparation containing a standardized amount of neutralizing antibody to Zika Virus. It is produced from plasma collected from healthy donors who have recovered from Zika infection (convalescent) and have high levels of neutralizing antibody for ZIKV; such collection is being done out of FDA licensed plasma collection establishments. The Phase 1 trial to evaluate the safety of ZIKV-IG completed enrollment in 2018. Several non-clinical studies are ongoing to evaluate efficacy and safety of ZIKV-IG in collaboration with several academic partners who have received funding from NIAID and other agencies.

Our Antibody Therapeutics business unit also has other product candidates addressing PHTs, including viral hemorrhagic fevers caused by Filoviruses (Ebola, Marburg and Sudan), among others.

Contract Development and Manufacturing

Our Contract Development and Manufacturing business unit, which is based on our established manufacturing infrastructure and expertise, consists of a broad range of contract development and manufacturing services, directed to both internal products owned by us as well as to third-party customers with specific and unique needs. These services include: pharmaceutical product process development, manufacturing and filling services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, laboratory analytical development support, aseptic filling, lyophilization, final packaging and accelerated and ongoing stability studies, as well as manufacturing of vial and pre-filled syringe formats, bulk drug product and finished units of clinical and commercial drugs. We provide these services for a wide variety of drug products – small molecule, biologics, and blood products – in all stages of development and commercialization, including over 30 licensed products which are currently sold in approximately 50 countries. Our third-party customers range from small biopharmaceutical companies to major multinational pharmaceutical companies. We perform work for this business unit at the following sites:

- *Camden (Baltimore, Maryland)*. Primarily supporting our Contract Development and Manufacturing business unit, our Camden facility has provided manufacturing services to more than 50 domestic and international customers and has manufactured over 20 commercial products distributed in approximately 50 countries. This fill/finish manufacturing site offers customers a broad portfolio of capabilities essential to their product development and commercialization efforts.
- *Bayview (Baltimore, Maryland)*. Our Bayview facility was designated by the HHS as a Center for Innovation in Advanced Development and Manufacturing ("CIADM") through a contract with BARDA in June 2012, one of three such sites in the U.S. Through this contract, we have responded to four Task Order Requests issued by BARDA for the development and manufacture of product candidates primarily addressing EID threats of high priority to the USG, including Zika and viral hemorrhagic fevers such as Ebola. In support of our Contract Development and Manufacturing business unit, our Bayview facility also provides manufacturing services to non-U.S. Government partners and customers.
- *Canton, Massachusetts*. Our Canton, Massachusetts facility is equipped with large-scale bioreactors for cell culture propagation and viral infection as well as downstream processing equipment for the production of live viral vaccine products, including ACAM2000. This site also operates as a contract manufacturing operation ("CMO") facility and we intend to expand on this capability.
- *Lansing, Michigan.* Our Lansing campus is our primary manufacturing location servicing our Vaccines and Anti-Infectives business unit for the

production of BioThrax and NuThrax. Our Lansing facilities also provide our Contract Development and Manufacturing business unit with capability for both small- and large- scale biologics bulk product manufacturing. We conduct CMO activities in our small-scale facility, Building 12, and we seek to market our available capacity in Lansing to enhance overall facility utilization.

- *Winnipeg, Manitoba, Canada.* Our facilities in Winnipeg contain the primary location for product development and manufacturing in support of our Antibody Therapeutics business unit. These facilities also support our Contract Development and Manufacturing business unit through product development and manufacturing support to a number of other customers.

Marketing and Sales

Our product sales can be divided into two primary categories: i) sales to the U.S. Government; and ii) commercial sales.

Government Procurement

For our Vaccines and Anti-Infectives, Antibody Therapeutics and Devices business units, our largest customers are the USG and domestic non-government organizations. All three business units share a team of dedicated marketing and sales personnel. We intend to use a similar approach to the marketing and sales of other product candidates that we either successfully develop or acquire. In addition to domestic sales, we sell our products to allied foreign governments as well as non-governmental organizations in foreign jurisdictions. For our non-U.S. sales, we use a combination of our employees as well as third-party marketing distributors and representatives to sell our products in key international markets, including Europe, the Middle East, Asia and the Pacific Rim. We anticipate engaging additional representatives as interest in countermeasures addressing PHTs increases outside the United States.

Our Contract Development and Manufacturing business unit is supported by a dedicated group of business development professionals qualified to represent the full spectrum of contract product development and manufacturing services that we offer.

Commercial Sales

NARCAN® Nasal Spray is sold commercially through physician directed or standing order prescriptions at retail pharmacies.

Vivotif and Vaxchora are vaccines intended for use by travelers heading to regions where there is a risk of exposure to certain infectious diseases and therefore are sold to channels that address travel health. We sell to both wholesalers and distributors as well as directly to healthcare practitioners. The primary commercial customers of Vivotif and Vaxchora are private travel clinics, retail pharmacies and integrated hospital networks.

Competition

Our products and product candidates intended for the treatment or prevention of CBRNE, EID threats, travelers' diseases and opioids face significant competition. Our products and any product or product candidate that we acquire or successfully develop and commercialize are likely to compete with current products and product candidates that are in development for the same indications. Specifically, the competition for our products and product candidates includes the following:

- ***BioThrax and NuThrax***. BioThrax is the only vaccine licensed by the FDA for the prevention of anthrax disease. However, we face potential future competition for the supply of anthrax vaccines to the USG if such products are approved. Altimmune, Inc., Pfenex Inc., Soligenix, Inc., Immunovaccine Inc. and NanoBio Corporation are each currently developing anthrax vaccine product candidates. The majority of these product candidates are in Phase 2 and we will continue to monitor the competitive landscape as we move NuThrax into Phase 3 and through to licensure.
- ***NARCAN® (naloxone HCl) Nasal Spray.*** With respect to NARCAN® Nasal Spray, we face competition from injectable naloxone, auto-injectors and improvised nasal kits. Amphastar Pharmaceuticals, Inc. competes with NARCAN® Nasal Spray with their naloxone injection product. Kaléo competes with NARCAN® Nasal Spray with their auto-injector known as EVZIO™ (naloxone HCl injection) Auto-Injector. In 2016, Teva Pharmaceuticals Industries Ltd. ("Teva") filed, and in 2018 Perrigo UK FINCO Limited Partnership ("Perrigo"), filed Abbreiviated New Drug Applications ("ANDAs," each an "ANDA") with the FDA seeking regulatory approval to market a generic version of NARCAN® Nasal Spray. Although NARCAN® Nasal Spray was the first FDA-approved naloxone nasal spray for the emergency reversal of opioid overdoses and has advantages over certain other treatments, we expect the treatment to face additional competition.
- ***ACAM2000***. ACAM2000 is the only FDA-licensed approved smallpox vaccine in the United States. Investigational stage competitor vaccine Imvamune® of Bavarian Nordic may be used in a smallpox emergency under the appropriate regulatory mechanism (*i.e.,* IND or EUA). Imvamune is approved in Canada and in the European Union where it is marketed under the trade name Imvanex®. It was designed for use in people for whom replicating smallpox vaccines are contraindicated and is indicated for use in immunocompromised patients, including HIV-infected individuals and those undergoing immunosuppressive therapy. A BLA was submitted by Bavarian Nordic to the FDA in October 2018.
- ***raxibacumab and Anthrasil***. Raxibacumab is the first FDA licensed fully human anthrax monoclonal antibody therapeutic and Anthrasil is the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of toxemia resulting from inhalational anthrax. However, Elusys Therapeutics, Inc. has obtained FDA licensure for Anthim® (obiltoxaximab) injection, indicated for the treatment and prophylaxis of inhalational anthrax.
- ***BAT***. Our botulinum antitoxin immune globulin product is the only heptavalent therapeutic licensed approved by the FDA and Health Canada for the treatment of botulism and has orphan drug designation. Other companies may be developing therapies aimed at treating or preventing botulism infections, however, direct competition is currently limited.
- ***VIGIV***. Our VIGIV product is the only therapeutic licensed approved by the FDA and Health Canada to address adverse events from smallpox vaccination with ACAM2000. Other companies may be developing therapies aimed at treating or preventing vaccinia infections; however, direct competition is currently limited. SIGA Technologies, Inc. is developing Tecovirimat (Arestvyr™, ST-26), an oral therapy that targets orthopox viruses such as vaccinia and potentially smallpox. Chimerix is also developing brincidofovir, a nucleotide analog lipid conjugate for treatment of smallpox.
- ***RSDL***. In the United States, the RSDL Kit is the only medical device cleared by the FDA to remove or neutralize chemical warfare agents and T-2 toxin from the skin. Internationally, various Ministries of Defense have procured Fullers Earth, Dutch Powder and French Powder as a preparedness countermeasure for the decontamination of liquid chemical weapons from the skin.
- ***Vivotif***®. Vivotif is the only licensed FDA-approved oral typhoid vaccine globally. In the markets where Vivotif is licensed, it competes with Sanofi Pasteur's Typhim VI® vaccine, an injectable polysaccharide typhoid vaccine.
- ***Vaxchora***®. In the United States, Vaxchora is the only FDA-licensed approved vaccine available indicated to prevent cholera. Dukoral®, an injectable cholera vaccine manufactured by Valneva, is available outside of the U.S.
- ***Trobigard***. Trobigard auto-injector delivers obidoxime chloride and atropine sulfate for emergency treatment of organophosphate nerve agent or

insecticide poisoning. Meridian Medical Technologies, a subsidiary of Pfizer, is currently the sole owner of FDA-approved nerve agent antidote auto-injector devices to the USG and many international allied governments. Internationally, the remaining market is fragmented and served by regional or national-based defense product manufacturers.

- § ***Contract Development and Manufacturing Services Business***. We compete for contract manufacturing service business with a number of biopharmaceutical product development organizations, contract manufacturers of biopharmaceutical products and university research laboratories, including, among others: Lonza Group Ltd., OSO BioPharmaceuticals Manufacturing, LLC, Par Pharmaceutical Companies, Inc., Jubilant Hollister-Stier Laboratories LLC (a subsidiary of Jubilant Life Sciences Limited), Patheon Inc., Hospira Inc., Ajinomoto Althea, Inc. (a subsidiary of Ajinomoto Co., Inc.), Cook Pharmica LLC (a subsidiary of Cook Group Inc.), and Albany Molecular Research, Inc. We also compete with in-house research, development and support service departments of other biopharmaceutical companies.

Geographical Reliance

For the years ended December 31, 2018, 2017 and 2016, our product sales revenue from U.S. customers as a percentage of total revenues were 73%, 67% and 58%, respectively.

MANUFACTURING

Our Lansing, Michigan site is a vertically integrated manufacturing campus and the location of our BioThrax manufacturing and NuThrax development operations. Located within the Lansing site is Building 55, our large-scale manufacturing facility, which was licensed by the FDA in August 2016 for the manufacture of BioThrax. This facility has the potential to manufacture up to 20 to 25 million doses of BioThrax annually on a single manufacturing train and has the physical footprint to add an additional manufacturing train, if needed. The manufacturing capabilities of Building 55 are central to our Vaccines and Anti-Infectives business unit. Our Lansing site also comprises biologics bulk product manufacturing capability (large- and small-scale), which we market to Contract Development and Manufacturing customers.

Our manufacturing facilities located at our Winnipeg, Manitoba, Canada, site are actively engaged in plasma-derived hyperimmune therapeutics manufacturing, chromatography-based plasma fractionation, downstream processing, aseptic filling, packaging and warehousing, quality assurance and control, and include development laboratories and office space. At these facilities, we manufacture and fill our hyperimmune specialty plasma products, including Anthrasil, BAT and VIGIV, and we conduct bulk manufacture our RSDL lotion. At these facilities, we also manufacture other hyperimmune products for contract manufacturing customers. The facilities at this site will play a key role in executing both product development and manufacturing activities in support of our Antibody Therapeutics and Contract Development and Manufacturing business units.

Our primary contract fill/finish services manufacturing site is located in Baltimore, Maryland, and is referred to as our "Camden Site." The Camden Site provides pharmaceutical product development and filling services for injectable and other sterile products, as well as process design, technical transfer, manufacturing validations, laboratory support, aseptic filling, lyophilization, final packaging and accelerated and ongoing stability studies support. This facility is an approved manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East as well as various other countries. The facility includes warehousing space used for cold-storage and freezer capacity to support contract manufacturing customers. Additionally, we intend for this facility to provide fill/finish services to many of our business units for our development and commercial-stage products and product candidates.

Our manufacturing facility focused on disposable manufacturing for viral and non-viral products is located in Baltimore, Maryland, and is referred to as our "Bayview Site." This facility is designed to take advantage of single-use bioreactor technology and to be capable of manufacturing several different products, including products derived from cell culture or microbial systems. In June 2012, we entered into a contract with BARDA, which established our Bayview Site as a CIADM. In May 2017 we completed work to expand this facility to double its original size to meet the needs of our customers. The facility is one of three centers designated by HHS to provide advanced development and manufacturing of MCMs to support the USG's national security and public health emergency needs. This facility has also been and will continue to be marketed to non-USG clients in need of bulk manufacturing services. We are currently in the process of pursuing FDA licensure for the transfer of bulk manufacturing of raxibacumab to our Bayview facility.

We also currently lease a packaging facility in Hattiesburg, Mississippi, at the University of Southern Mississippi's Accelerator, a technology innovation and commercialization center. This facility is equipped to package RSDL. RSDL bulk lotion that is manufactured in Winnipeg is shipped to Hattiesburg, Mississippi, for combination with RSDL sponges, which are further manufactured, packaged and then released for sale. All RSDL packets are packaged at this facility.

In October 2017, in connection with our acquisition of the ACAM2000 business from Sanofi, we acquired a live viral manufacturing facility and a leased office and warehouse space, both in Canton, Massachusetts, and a leased cGMP live viral fill/finish facility in Rockville, Maryland. Our Rockville facility is an FDA-licensed manufacturing facility under the regulatory regimes of the United States, Australia and Singapore. In November 2017, we received FDA approval of our supplemental BLA for the transfer of the upstream portion of the manufacturing process of ACAM2000 to our live viral manufacturing facility in Canton, Massachusetts.

In October 2018, in connection with our acquisition of PaxVax, we acquired a live viral manufacturing facility located in Bern, Switzerland and a fill/finish facility located in San Diego, California.

Supplies and Raw Materials

We currently rely on contract manufacturers and other third parties to manufacture some of the supplies we require for pre-clinical studies and clinical trials, as well as supplies and raw materials used in the production of our products. Typically, we acquire these supplies and raw materials on a purchase order basis and, when possible, in quantities we believe adequate to meet our needs. We obtain Alhydrogel® adjuvant 2%, used to manufacture BioThrax and NuThrax, from a single-source supplier for which we have no alternative source of supply. However, we maintain stored supplies of this adjuvant sufficient to meet our expected manufacturing needs for these products. We also utilize single-source suppliers for other raw materials in our manufacturing processes.

We utilize single source suppliers for all components of NARCAN® Nasal Spray. It is manufactured by a third party, which operates a full service offering from formulation to final packaging. Materials for production of NARCAN® Nasal Spray, such as Naloxone API and other excipients, along with the vial, stopper and device are produced around the world by other third parties and delivered to the primary manufacturer and released to manufacturing following appropriate testing.

INTELLECTUAL PROPERTY

We actively seek to protect the intellectual property that arises from our activities. It is our policy to respect the intellectual property rights of others. In general, and where practicable, we pursue patent protection for new and innovative processes and products that we develop. The duration of and the type of protection afforded by a patent varies on a product-by-product basis and country-to-country basis and depends upon many factors including the type of patent, the scope of its coverage, the availability of regulatory-related extensions or administrative term adjustments, the availability of legal remedies in a particular country, and the validity and enforceability of the patents. In some cases, we may decide that the best way to protect certain intellectual property is to retain

proprietary information as trade secrets rather than apply for patent protection, which requires disclosure of the proprietary information to the public. We take a number of measures to protect our trade secrets and other confidential information, including entering into confidentiality agreements with employees and third parties. In general, and where practicable, we also pursue registered trademarks for our products and product candidates. We are a party to a number of license agreements under which we license patents, patent applications, trademarks, and other intellectual property. We enter into these agreements to augment our own intellectual property and to secure freedom to operate where necessary. These agreements sometimes impose various commercial diligence and financial payment obligations on us. We expect to continue to enter into these types of agreements in the future.

REGULATION

Regulations in the United States and other countries have a significant impact on our product development, manufacturing and marketing activities.

Government Contracting

Our status as a USG contractor means that we are subject to various statutes and regulations, including:

- § the Federal Acquisition Regulation ("FAR") and agency-specific regulations supplemental to FAR, which comprehensively regulate the award, formation, administration and performance of government contracts;
- § the Defense Federal Acquisition Regulations ("DFARs") and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of DoD government contracts;
- § the Department of State Acquisition Regulation ("DOSAR") which regulates the relationship between a Department of State organization and a contractor or potential contractor;
- § business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;
- § export and import control laws and regulations, including but not limited to ITAR (International Traffic in Arms Regulations); and
- § laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

USG agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. These regulations can impose stricter penalties than those normally applicable to commercial contracts, such as criminal and civil liability and suspension and debarment from future government contracting. In addition, pursuant to various regulations, our government contracts can be subject to unilateral termination or modification by the government for convenience, detailed auditing and accounting systems requirements, statutorily controlled pricing, sourcing and subcontracting restrictions and statutorily mandated processes for adjudicating contract disputes.

Project BioShield. The Project BioShield Act of 2004 ("Project BioShield") provides expedited procedures for bioterrorism-related procurement and the awarding of research grants, making it easier for HHS to rapidly commit funds to countermeasure projects. Project BioShield relaxes procedures under the FAR for procuring property or services used in performing, administering or supporting biomedical countermeasure research and development. In addition, if the Secretary of HHS deems that there is a pressing need, Project BioShield authorizes the Secretary to use an expedited award process, rather than the normal peer review process, for grants, contracts and cooperative agreements related to biomedical countermeasure research and development activity. Under Project BioShield, in limited specified circumstances, HHS can contract to purchase unapproved countermeasures for the SNS and authorize the emergency use of medical products that have not yet been approved by the FDA.

First Responders Act. The First Responder Anthrax Preparedness Act of 2016 directs the Secretary of Homeland Security, in consultation with the Secretary of HHS, to establish a pilot program to provide short-dated vaccines from the SNS to emergency response providers on a voluntary basis.

Public Readiness and Emergency Preparedness Act. The Public Readiness and Emergency Preparedness Act ("PREP Act") was signed into law in December 2005. The PREP Act creates liability protection for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is intended to provide liability protection from claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations identifying BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT and VIGIV, as covered countermeasures. These declarations expire in 2022. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct and, accordingly, the PREP Act may not provide adequate protection from all claims made against us.

Support Anti-Terrorism by Fostering Effective Technology Act of 2002. The Support Anti-Terrorism by Fostering Effective Technology Act of 2002 ("SAFETY Act") is intended to create product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Certain of our products, namely BioThrax and RSDL, are certified anti-terrorism products covered under the protections of the SAFETY Act. Although we are covered by the benefits of the SAFETY Act for BioThrax and RSDL, the SAFETY Act may not provide adequate protection from all claims made against us.

Product Development for Therapeutics and Vaccines

Pre-Clinical Testing. Before beginning testing of compounds in human subjects in the United States, stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing generally includes both *in vitro*, or in an artificial environment outside of a living organism, and *in vivo*, or within a living organism, laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. We generally perform pre-clinical safety and efficacy testing on our product candidates before we initiate clinical trials.

Animal Rule. For product candidates that are intended to treat or prevent infection from rare life-threatening diseases, conducting controlled clinical trials with human patients to determine efficacy may be unethical or unfeasible. Under regulations issued by the FDA in 2002, often referred to as the "Animal Rule," under some circumstances, approval of such product candidates can be based on clinical data from trials in healthy subjects that demonstrate adequate safety and immunogenicity as well as efficacy data from adequate and well-controlled animal studies. Among other requirements, the animal studies must establish that the drug or biological product is reasonably likely to produce clinical benefit in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and efficacy in humans, these studies add complexity and uncertainty to the testing and approval process. In addition, products approved under the Animal Rule are subject to additional requirements, including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

Investigational New Drug Application. Before clinical testing may begin, the results of pre-clinical testing, together with manufacturing information, analytical data and any other available clinical data or literature, must be submitted to the FDA as part of an IND application. The sponsor must also include an initial protocol detailing the first phase of the proposed clinical investigation. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical studies in human volunteers. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA imposes a clinical hold within that 30-day period.

Clinical Trials. Clinical trials generally involve the administration of the product candidate to healthy human volunteers or to patients under the supervision of a qualified physician (also called an investigator) pursuant to an FDA-reviewed protocol. In certain cases, described below, animal studies may be used in place of human studies. Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another and trial designs vary depending on the Therapeutic or Prophylactic nature of the product. Clinical trials must be conducted under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria, if any, to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

- § Phase 1 clinical trials test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, for early evidence regarding efficacy.

- § Phase 2 clinical trials involve a small number of patients with the target disease or disorder and seek to assess the efficacy of the drug for specific indications to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.

- § Phase 3 clinical trials consist of expanded, larger-scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product candidate using a specific dosing regimen. The safety and efficacy data generated from Phase 3 clinical trials typically form the basis for FDA approval of the product candidate.

- § Phase 4 clinical trials are sometimes conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific patient population. As part of a product approval, the FDA may require that certain Phase 4 studies, which are sometimes called post-marketing commitment studies, be conducted post-approval.

Good Clinical Practice. All phases of clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations and Good Clinical Practices ("GCP") which are ethical and scientific quality standards for conducting, recording and reporting clinical trials to assure that the data and reported results are credible and accurate and that the rights, safety and well-being of trial participants are protected.

Marketing Approval – Biologics, Drugs and Vaccines

Biologics License Application/New Drug Application. For large molecule products, including products such as vaccines, products derived from blood and blood components, and antibodies and other recombinant proteins, all data obtained from a development program, including research and product development, manufacturing, pre-clinical and clinical trials, labeling and related information are submitted in a BLA to the FDA and in similar regulatory filings with the corresponding agencies in other countries for review and approval. For small molecule drugs, this information is submitted in a new drug application ("NDA") filing. The submission of an application is not a guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application and request additional information rather than accept the application for filing, in which case the application must be resubmitted with the supplemental information. Once an application is accepted for filing, the Prescription Drug User Fee Act ("PDUFA") requires the FDA to review the application within 10 months of its 60-day filing date, although in practice, longer review times may occur.

In addition, under the Pediatric Research Equity Act of 2003 ("PREA"), BLAs, NDAs and certain supplements must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug or biologic for an indication for which orphan drug designation has been granted.

In reviewing a BLA or NDA, the FDA may grant approval, request more information or data, or deny the application if it determines the application does not provide an adequate basis for approval. Even if such additional information and data are submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. The receipt of regulatory approval often takes many years, involving the expenditure of substantial financial resources. The speed with which approval is granted often depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits of the product candidate as demonstrated in clinical trials. The FDA may also impose conditions upon approval. For example, it may require a Risk Evaluation and Mitigation Strategy ("REMS") for a product. This can include various required elements, such as publication of a medication guide, patient package insert, a communication plan to educate health care providers of the drug's risks and/or restrictions on distribution and use such as limitations on who may prescribe or dispense the drug. The FDA may also significantly limit the indications approved for a given product and/or require, as a condition of approval, enhanced labeling, special packaging or labeling, post-approval clinical trials, expedited reporting of certain adverse events, pre-approval of promotional materials or restrictions on direct-to-consumer advertising, any of which could negatively impact the commercial success of a product.

Fast Track Designation. The FDA may designate a product as a fast track drug if it is intended for the treatment of a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for this disease or condition. Sponsors granted a fast track designation for a drug are granted more opportunities to interact with the FDA during the approval process and are eligible for FDA review of the application on a rolling basis, before the application has been completed. The FDA granted fast track status to NuThrax in June 2011 and to ZIKV-IG in December 2017.

Orphan Drugs. Under the Orphan Drug Act, an applicant can request the FDA to designate a product as an "orphan drug'' in the United States if the drug is intended to treat an orphan, or rare, disease or condition. A disease or condition is considered orphan if it affects fewer than 200,000 people in the United States. A manufacturer must request orphan drug designation prior to submitting a BLA or NDA. Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity (afforded to the first applicant to receive approval for an orphan designated drug) prevents FDA approval of applications by others for the same drug for the designated orphan disease or condition. The FDA may approve a subsequent application from another applicant if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. A grant of an orphan designation is not a guarantee that a product will be approved.

Our products with current orphan drug exclusivity in the United States include the following:

- § BioThrax for post-exposure prophylaxis of disease following suspected or confirmed *B. anthracis* exposure, when administered in conjunction with recommended antibacterial drugs, with exclusivity though November 2022;
- § raxibacumab for the treatment of adult and pediatric patients with inhalational anthrax in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or not appropriate, with exclusivity through December 2019;
- § Anthrasil for the treatment of toxemia associated with inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs, with exclusivity through March 2022; and

§ BAT for the treatment of suspected or documented exposure to botulinum neurotoxin A, B, C, D, E, F or G, with exclusivity through March 2020.

Post-Approval Requirements. Any drug, biologic or medical device product for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, cGMPs and restrictions on advertising and promotion. Adverse events that are reported after marketing approval can result in additional limitations being placed on the product's distribution or use and, potentially, withdrawal or suspension of the product from the market. In addition, the FDA has post-approval authority to require post-approval clinical trials and/or safety labeling changes if warranted by the appearance of new safety information. In certain circumstances, the FDA may impose a REMS after a product has been approved. Facilities involved in the manufacture and distribution of approved products are required to register their facility with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other laws. The FDA also closely monitors advertising and promotional materials we may disseminate for our products for compliance with restrictions on off-label promotion and other laws. We may not promote our products for conditions of use that are not included in the approved package inserts for our products. Certain additional restrictions on advertising and promotion exist for products that have so-called "black box warnings" in their approved package inserts, such as Anthrasil and VIGIV in the United States.

Vaccine and Therapeutic Product Lot Release and FDA Review. Because the manufacturing process for biological products is complex, the FDA requires for many biologics, including most vaccines and immune globulin products, that each product lot undergo thorough testing for purity, potency, identity and sterility. All of our vaccines and immune globulin products are subject to lot release protocols by the FDA and other regulatory agencies. The length of the review process depends on a number of factors, including reviewer questions, license supplement approval, reviewer availability and whether our internal testing of product samples is completed before or concurrently with regulatory agency testing, if applicable.

Priority Review Vouchers. In 2007, the Food and Drug Administration Amendments Act added Section 524 to the Food, Drug, and Cosmetic Act and established the Neglected Tropical Disease Priority Review Voucher ("PRV") program. This PRV program was expanded in 2012 by the Food and Drug Administration Safety and Innovation Act to include rare pediatric diseases. In December 2016, the 21st Century Cures Act established a PRV program within the FDA for MCMs for chemical, biological, radiological or nuclear threats, and those vaccines, therapeutics and MCMs, that prevent or treat material threat agents as identified in the Public Health Service Act. Under the PRV program, upon approval of a qualified product, companies receive a special voucher which allows them to have a drug reviewed under FDA's priority review system, with the anticipation that it will accelerate the regulatory review to get the product to market more rapidly. Recipients of a PRV may transfer that voucher to another party for consideration.

Several of our investigational stage product candidates may be eligible for PRV under multiple PRV programs upon the product approval. We believe that ZIKV-IG (NP024), a human polyclonal antibody therapeutic being developed as a prophylaxis and treatment for Zika infections in at risk populations may have the potential for a PRV under the Neglected Tropical Disease PRV program. We believe that the Chikungunya VLP vaccine, being developed for prevention of disease caused by chikungunya infections, may have the potential for a PRV under the Neglected Tropical Disease PRV program and under the MCM PRV program. We also believe that rVSV-Quad, rVSV-Lassa, rVSV-Ebola, rVSV-Marburg and rVSV-Sudan, the candidate viral hemorrhagic fever virus vaccines, may have potential for a PRV under either the Neglected Tropical Disease PRV program or the MCM PRV program. However, there can be no assurances that any of these candidates will obtain PRV status.

Marketing Approval – Devices

Devices may fall within the definition of a Medical Device or may be a Combination Product including both a device for delivery of a drug product and the drug product itself. Medical Devices are also subject to FDA clearance or approval and extensive regulation under the U.S. Food, Drug and Cosmetic Act ("FDCA"). Under the FDCA, medical devices are classified into one of three classes: Class I, Class II or Class III. The classification of a device generally depends on the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness. The RSDL Kit is regulated as a non-restricted Class II medical device. Our Trobigard auto-injector product is not currently approved or cleared by the FDA or any similar regulatory body and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

§ Class I devices are those for which safety and effectiveness can be assured by adherence to a set of general controls. These general controls include compliance with the applicable portions of the FDA's Quality System Regulation ("QSR") which sets forth requirements for manufacturing practices, record keeping, reporting of adverse medical events, labeling and promotion only for cleared or approved intended uses.

§ Class II devices are also subject to these general controls and to any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Review and clearance by the FDA for these devices is typically accomplished through the 510(k)-pre-market notification procedure. When 510(k) clearance is sought, a sponsor must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a device approved by the FDA after May 28, 1976. This previously-cleared device is called the predicate device. If the FDA agrees that the proposed device is substantially equivalent to the predicate device, then 510(k) clearance to market will be granted. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require pre-market approval. If a proposed device is substantially equivalent to a predicate device that was cleared prior to May 28, 1976, the proposed device is cleared based on a pre-amendment and is cleared as an unclassified device.

§ A Class III device requires approval of a pre-market application ("PMA") which is an expensive, lengthy and uncertain process requiring many years to complete. Clinical trials are almost always required to support a PMA. These trials generally require submission of an application for an investigational device exemption ("IDE"). An IDE must be supported by pre-clinical data, such as animal and laboratory testing results, which show that the device is safe to test in humans and that the study protocols are scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and is eligible for more abbreviated investigational device exemption requirements.

Both before and after a medical device is commercially distributed, manufacturers and marketers of the device have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, record keeping, reports of adverse events, labeling and other information to identify potential problems with marketed medical devices. Device manufacturers are subject to periodic and unannounced inspection by the FDA for compliance with cGMP requirements that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, servicing, labeling, storage, installation and distribution of all finished medical devices intended for human use. If the FDA finds that a manufacturer has failed to comply or that a medical device is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, ranging from a public warning letter to more severe actions, including:

§ fines, injunctions, and civil penalties;
§ recall or seizure of products;
§ operating restrictions, partial suspension or total shutdown of production;
§ refusal of requests for 510(k) clearance or PMA approval of new products;
§ withdrawal of 510(k) clearance or PMA approvals already granted; and
§ criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device. The FDA also administers certain controls over the export of medical devices from the United States, as international sales of medical devices that have not received FDA approval are subject to FDA export requirements.

Combination Products, of the type described above, are subject to the BLA/NDA regulatory regime. Our Trobigard auto-injector is a combination product and is not currently approved or cleared by the FDA or any similar regulatory body and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Abbreviated New Drug Applications and Section 505(b)(2) New Drug Applications. Most drug products obtain FDA marketing approval pursuant to an NDA for innovator products, or an ANDA for generic products. Relevant to ANDAs, the Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are also referred to as listed drugs). Because the safety and efficacy of listed drugs have already been established by the brand company (sometimes referred to as the innovator), the FDA does not require a demonstration of safety and efficacy of generic products. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the API is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling and stability data.

The third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings with respect to certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for certain label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired. Thus approval of a Section 505(b)(2) NDA or ANDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA or Section 505(b)(2) applicant.

Foreign Regulation

Currently, we maintain a commercial presence in the United States and Canada as well as select foreign countries. We intend to further expand our commercial presence to additional foreign countries and territories. In the European Union, medicinal products are authorized following a process similarly demanding as the process required in the United States. Medicinal products must be authorized in one of two ways, either through the decentralized procedure, which provides for the mutual recognition procedure of national approval decisions by the competent authorities of the European Union ("EU") Member States or through the centralized procedure by the European Commission, which provides for the grant of a single marketing authorization that is valid for all EU member states. The authorization process is essentially the same irrespective of which route is used. We are also subject to many of the same continuing post-approval requirements in the EU as we are in the United States (*e.g.,* good manufacturing practices). Additionally, each foreign country subjects medical devices to its own regulatory requirements. In the European Union, a harmonized medical device directive legislates approval requirements. Within this framework, the CE Mark, an attestation of conformity with the essential health, safety and environmental requirements and compliance with relevant European Union legislation, allows for the legal marketing of the product in all European Economic Area member states. Additionally, to the extent that a product is marketed outside of the United States, a facility may also be registered with applicable ex-U.S. regulatory authorities, who may also require inspections for compliance with local marketing regulations.

Anti-Corruption Laws

As part of the Affordable Care Act, the federal government enacted the Physician Payment Sunshine Act. Manufacturers of drugs are required to publicly report payments and transfers of value made to physicians and teaching hospitals. This information is posted on a public website. Failure to timely and accurately submit required information could subject us to civil penalties.

Our operations are also subject to compliance with the Foreign Corrupt Practices Act ("FCPA") which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We also may be implicated under the FCPA by the activities of our partners, collaborators, contract research organizations, vendors or other agents. As a public company, the FCPA also requires us to make and keep books and records that accurately and fairly reflect all of our transactions and to devise and maintain an adequate system of internal accounting controls. Our operations are also subject to compliance with the U.K. Bribery Act, which applies to bribery activities both in the public and private sector, Canada's Corruption of Foreign Public Officials Act and similar laws in other countries.

Other Industry Regulation

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to the use of data, safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, export, use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents used in connection with our product development, are or may be applicable to our activities.

EMPLOYEES

As of February 15, 2019, we had 1,705 full-time employees. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

AVAILABLE INFORMATION

Our common stock is traded on the New York Stock Exchange under the ticker symbol "EBS." Our principal executive offices are located at 400 Professional Drive, Suite 400, Gaithersburg, Maryland 20879. Our telephone number is (240) 631-3200, and our website address is www.emergentbiosolutions.com. We maintain a website at www.emergentbiosolutions.com. We make available, free of charge on our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission (the "SEC").

We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we intend to make available on our website all disclosures that are required to be posted by applicable law, the rules of the SEC or the New York Stock Exchange listing standards regarding any amendment to, or waiver of, our code of business conduct and ethics. We have included our website address as an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of, or incorporated by reference into, this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors in addition to the other information in this Annual Report on Form 10-K when evaluating our business because these risk factors may have a significant impact on our business, financial condition, operating results or cash flows. If any of the risks described below or in subsequent reports we file with the SEC actually occur, they may materially harm our business, financial condition, operating results or cash flows. Additional risks and uncertainties that we have not yet identified or that we presently consider to be immaterial may also materially harm our business, financial condition, operating results or cash flows. The discussion of these factors is incorporated by reference into and considered an integral part of Part II, Item 7, "Management's Discussion and Analysis of Financial Conditions and Results of Operations."

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from sales of BioThrax to our largest customer, the USG. If the USG's demand for and/or funding for procurement of BioThrax is substantially reduced, our business, financial condition, operating results and cash flows would be materially harmed.

We derive a substantial portion of our current and expected future revenues from sales of BioThrax, our anthrax vaccine licensed by the FDA to the USG. In December 2016, we signed a follow-on procurement contract with the CDC for the delivery of approximately 29.4 million doses of BioThrax for placement into the SNS over a five-year period ending in September 2021. The potential value of this contract is approximately $911 million if all procurement options are exercised.

The procurement of doses of BioThrax by the CDC is subject to the availability of funding. We have no certainty that funding will be made available for the procurement of doses under the CDC contract. If the SNS priorities change, funding to procure doses of BioThrax may be limited or not available, and our business, financial condition and operating results and cash flows would be materially harmed. The success of our business and our future operating results are significantly dependent on funding for the procurement of BioThrax and the terms of our BioThrax sales to the USG, including the price per dose, the number of doses and the timing of deliveries.

Our submission of NuThrax for EUA pre-approval and eventual FDA licensure may not be approved by the FDA in a timely manner or at all. Delays in our ability to achieve such pre-approval and licensure could prevent us from realizing the full potential value of our BARDA contract for the advanced development and procurement of NuThrax.

In September 2016, we entered into a contract with HHS through BARDA for the advanced development and procurement of NuThrax, our next generation anthrax vaccine candidate. The contract, as modified in March 2017, is valued at up to approximately $1.5 billion.

We recently submitted an application with the FDA for EUA pre-approval of NuThrax, and although there can be no assurances, we currently anticipate that the FDA could authorize NuThrax for emergency use as early this year, triggering deliveries of NuThrax to the SNS for use in an emergency situation as early as this year. However, the FDA does not have review deadlines with respect to such submissions and, therefore, the timing of any approval of our EUA pre-approval submission is uncertain. We cannot guarantee that the FDA will review our data in a timely manner, or that the FDA will accept the data when reviewed. The FDA may decide that our data are insufficient for EUA pre-approval and require additional pre-clinical, clinical or other studies and refuse to approve our application. If we are unsuccessful in obtaining EUA pre-approval for NuThrax and eventual FDA licensure in a timely manner or at all, we may not be able to realize the full potential value of the contract, which could have a material adverse effect on our future business, financial condition, operating results and cash flows.

In addition, if priorities for the SNS change, funding to procure any future doses of NuThrax may be limited or not available, and our future business, financial condition, operating results and cash flows could be materially harmed.

Our USG procurement and development contracts require ongoing funding decisions by the USG. Reduced or discontinued funding of these contracts could cause our business, financial condition, operating results and cash flows to suffer materially.

The USG is the principal customer for our PHT-focused MCMs and is the primary source of funds for the development of our product candidates in our development pipeline, most notably our NuThrax product candidate. We anticipate that the USG will also be a principal customer for those MCMs that we successfully develop within our existing product development pipeline, as well as those we acquire in the future. Additionally, a significant portion of our revenue comes from USG development contracts and grants. Over its lifetime, a USG procurement or development program may be implemented through the award of many different individual contracts and subcontracts. The funding for such government programs is subject to Congressional appropriations, generally made on a fiscal year basis, even for programs designed to continue for several years. For example, sales of BioThrax to be supplied under our procurement contract with the CDC are subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations and stringent budgetary constraints.

Additionally, our government-funded development contracts typically give the USG the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. For example, the September 2016 contract award from BARDA for the development and delivery to the SNS of NuThrax for post-exposure prophylaxis of anthrax disease consists of a five-year base period of performance valued at approximately $200 million. The contract award also includes options for the delivery of additional doses of NuThrax to the SNS and options for an additional clinical study and post-marketing commitments which if both were to be exercised in full, would increase the total contract value to up to $1.5 billion. If levels of government expenditures and authorizations for public health countermeasure preparedness decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the USG otherwise declines to exercise its options under our existing contracts, our revenues would suffer, as well as our business, financial condition, operating results and cash flows.

There can be no assurance that we will be able to secure follow-on procurement contracts with the USG upon the expiration of any of our current product procurement contracts.

The majority of our revenue is substantially dependent upon product procurement contracts with the USG and foreign governments for our PHT products. Upon the expiration of a procurement contract, we may not be able to negotiate a follow-on procurement contract for the particular product for a similar product volume, period of performance, pricing or other terms, or at all. The inability to secure a similar or increased procurement contract could materially affect our revenues and our business, financial condition, operating results and cash flows could be harmed. For example, although there are remaining deliverables under the contract, the CDC procurement contract for ACAM2000 that we acquired in our acquisition of the ACAM2000 business from Sanofi expired on March 31, 2018. The BARDA procurement contract for raxibacumab that we acquired in our acquisition of raxibacumab from Human Genome Sciences, Inc. and GlaxoSmithKline LLC, collectively referred to as GSK, will expire in November 2019. Our CDC procurement contract for BioThrax expires in 2021. We intend to negotiate follow-on procurement contracts for each of our PHT products upon the expiration of a related procurement contract, including our procurement contract for ACAM2000, but there can be no assurance that we will be successful obtaining any follow-on contracts. Even if we are successful in negotiating a follow-on procurement contract, it may be for a lower product volume, over a shorter period of performance or be on less favorable pricing or other terms. An inability to secure follow-on procurement contracts for our products could materially and adversely affect our revenues, and our business, financial condition, operating results and cash flows could be harmed.

The government contracting process is typically a competitive bidding process and involves unique risks and requirements.

Our business involves government contracts and grants, which may be awarded through competitive bidding. Competitive bidding for government contracts presents many risks and requirements, including:

- the possibility that we may be ineligible to respond to a request for proposal issued by the government;
- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- in the event our competitors protest or challenge contract or grant awards made to us pursuant to competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in the termination, reduction or modification of the awarded contract.

The USG may choose not to award us future contracts for either the development of our new product candidates or for the procurement of our existing products addressing PHTs and may instead award such contracts to our competitors. If we are unable to secure particular contracts, we may not be able to operate in the market for products that are provided under those contracts. Additionally, if we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs or resources that we will be required to secure and, if applicable, perform under such contract awards, our growth strategy and our business, financial condition and operating results and cash flows could be materially and adversely affected.

Laws and regulations affecting government contracts make it costlier and more difficult for us to successfully conduct our business. Failure to comply with these laws could result in significant civil and criminal penalties and materially damage our reputation and relationship with the USG, which could have a material adverse effect on our business, financial condition, operating results and cash flows.

As a manufacturer and supplier of MCMs to the USG addressing PHTs, we must comply with numerous laws and regulations relating to the procurement, formation, administration and performance of government contracts. These laws and regulations govern how we transact business with our government clients and, in some instances, impose additional costs and related obligations on our business operations. Among the most significant government contracting regulations that affect our business are:

- the FAR and agency-specific regulations supplemental to FAR, which comprehensively regulate the award, formation, administration and performance of government contracts;
- the DFARs and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of DoD government contracts;
- the DOSAR, which regulates the relationship between a Department of State organization and a contractor or potential contractor;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;
- export and import control laws and regulations, including but not limited to International Traffic in Arms Regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

USG agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. Even though we take significant precautions to identify, prevent and deter fraud, misconduct and non-compliance, we face the risk that our personnel or outside partners may engage in misconduct, fraud or improper activities. If we are audited and such audit were to uncover improper or illegal activities, we could be subject to civil and criminal penalties, administrative sanctions, including suspension or debarment from government contracting, and suffer significant reputational harm. Loss of our status as an eligible government contractor would have a material adverse effect on our business.

The amount we are paid under our fixed price government procurement contracts is based on estimates we have made of the time, resources and expenses required for us to perform under those contracts. If our actual costs exceed our estimates, we may not be able to earn an adequate return or may incur a loss under these contracts, which could harm our operating results and materially reduce our net income.

Our current procurement contracts with HHS and the DoD are fixed price contracts. We expect that future procurement contracts we successfully secure with the USG would also be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of such a contract or cause a loss, which could harm our operating results and materially reduce our net income.

Unfavorable provisions in government contracts, some of which may be customary, may subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on our business, financial condition, operating results and cash flows.

Government contracts customarily contain provisions that give the USG substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the USG to:

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders, if funds for contract performance for any subsequent year become unavailable;
- decline, in whole or in part, to exercise an option to purchase product under a procurement contract or to fund additional development under a development contract;
- decline to renew a procurement contract;
- claim rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- take actions that result in a longer development timeline than expected;

- § direct the course of a development program in a manner not chosen by the government contractor;
- § suspend or debar the contractor from doing business with the government or a specific government agency;
- § pursue civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and
- § control or prohibit the export of products.

Generally, government contracts contain provisions permitting unilateral termination or modification, in whole or in part, at the USG's convenience. Under general principles of government contracting law, if the USG terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the USG terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. All of our contracts, both development and procurement, with the USG, are terminable at the USG's convenience with these potential consequences.

In addition, our USG contracts grant the USG the right to use technologies developed by us under the government contract or the right to share data related to our technologies, for or on behalf of the USG. Under our USG contracts, we might not be able to prohibit third parties, including our competitors, from accessing such technology or data, including intellectual property, in providing products and services to the USG.

The loss of any of our non-exclusive, sole-source or single source suppliers or an increase in the price of inventory supplied to us could have an adverse effect on our business, financial condition and results of operations.

We purchase certain supplies used in our manufacturing processes from non-exclusive, or single sources due to quality considerations, costs or constraints resulting from regulatory requirements, including key components for NARCAN® Nasal Spray (Naloxone API, along with the vial, stopper and device). Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products, and the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such a supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to cease operations. Any reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or an increase in the price of those materials or components could adversely affect our business, financial condition and results of operations.

Additionally, any failure by us to forecast demand for, or our suppliers to maintain an adequate supply of, the raw material and finished product for producing NARCAN® Nasal Spray could result in an interruption in the supply of NARCAN® Nasal Spray and a decline in sales of the product.

REGULATORY AND COMPLIANCE RISKS

Our long-term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates we develop or acquire and, if we are not successful, our business, financial condition, operating results and cash flows may suffer.

Our product candidates and the activities associated with their development, including testing, manufacture, recordkeeping, storage and approval, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Except under limited circumstances related to certain government sales, failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate.

In the United States, to obtain approval from the FDA to market any of our future biologic products, we will be required to submit a BLA to the FDA. Ordinarily, the FDA requires a company to support a BLA with substantial evidence of the product candidate's safety and efficacy in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase 3 safety and efficacy trials conducted in patients with the disease or condition being targeted.

However, NuThrax and many of our MCM product candidates, for example, are subject to a different regulatory approval pathway under the FDA's "Animal Rule." The Animal Rule provides a regulatory pathway for drug and biologic products targeting indications for which human efficacy studies are not feasible or would be unethical. Instead, efficacy must be demonstrated, in part, by utilizing animal models rather than testing in humans. We cannot guarantee that the FDA will permit us to proceed with licensure of NuThrax or any of our PHT MCM candidates under the Animal Rule. Even if we are able to proceed pursuant to the Animal Rule, the FDA may decide that our data are insufficient to support approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Furthermore, products approved under the Animal Rule are subject to certain additional post-marketing requirements. For example, to the extent feasible and ethical, manufacturers of products approved pursuant to the Animal Rule must conduct post-marketing studies, such as field studies, to verify and describe the product candidate's clinical benefit and to assess its safety when used as indicated. We cannot guarantee that we will be able to meet this regulatory requirement even if one or more of our product candidates are approved under the Animal Rule.

The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process may cause delays in the approval or rejection of an application.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient to support approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We intend to transfer the manufacturing of raxibacumab, which we acquired from GSK, to our bulk and fill finish facilities in Baltimore, Maryland, and this transfer of manufacturing operations requires FDA approval.

Under our arrangements with GSK for our acquisition of the raxibacumab product, we will continue to purchase product from GSK to satisfy deliveries to the SNS under the current BARDA contract, which expires in November 2019. We intend to seek FDA approval to transfer the manufacturing of raxibacumab to our Baltimore, Maryland bulk and fill finish manufacturing facilities and currently anticipate FDA approval of this technology transfer in 2020. Approval of this technology transfer may involve complications or may not be secured on a timely basis or at all. Any delay in the approval of this anticipated technology transfer would delay our expected benefits and synergies from this product acquisition and could materially harm our revenues and our business, financial condition, operating results and cash flows could be harmed. Until approval of this technology transfer, we must rely on GSK to supply product to us to satisfy deliveries to the SNS under the BARDA contract, and GSK may fail to meet delivery obligations, which could result in our inability to satisfy requirements under the BARDA contract.

Even after regulatory approval is received, if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market.

Any vaccine, therapeutic product or medical device for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. Our approved products are subject to these requirements and ongoing review. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to potency and stability, quality control, quality assurance, restrictions on advertising and promotion, import and export restrictions and recordkeeping requirements. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Our regulators enforce cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our facilities where Canadian marketed products are produced, or related formulation and filling operations are conducted. The FDA, Health Canada, and other foreign regulatory agencies conduct periodic inspections of our facilities. Following several of these inspections, regulatory authorities

have issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, regulatory authorities find that we are not in substantial compliance with all applicable requirements, or if they are not satisfied with the corrective actions we take, our regulators may undertake enforcement action against us, which may include:

- § warning letters and other communications;
- § product seizure or withdrawal of the product from the market;
- § restrictions on the marketing or manufacturing of a product;
- § suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements to approved applications;
- § fines or disgorgement of profits or revenue; and
- § injunctions or the imposition of civil or criminal penalties.

Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. For instance, our products are tested regularly to determine if they satisfy potency and stability requirements for their required shelf lives. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval. Regulatory approval may also contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post-approval events, our business, financial condition, operating results and cash flows could be materially and adversely affected.

Additionally, companies may not promote drugs for "off-label" uses (*i.e.,* uses that are not described in the product's labeling and that differ from those approved by the applicable regulatory agencies). A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies (such as entering into corporate integrity agreements with the USG), as well as criminal sanctions. If our employees or agents engage in "off-label" marketing of any of our products, we could be subject to civil or criminal investigations, monetary and injunctive penalties, which could adversely impact our ability to conduct business in certain markets, negatively affect our business, financial condition, operating results and cash flows, and damage our reputation.

One or more of our products could be subject to early generic competition.

One or more of our products is approved under the provisions of the FDCA, which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on physicians or payers to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to the FDA in which the generic manufacturer claims that the innovator's patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement. If the patent owner files suit within 45 days of receiving notice from an ANDA filer, the patent owner is entitled to receive a 30 month stay on the FDA's ability to give final approval for the generic product that is the subject of the ANDA.

In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the applicability of patents listed in the FDA's Approved Drug Products List with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, on a wide array of innovative therapeutic products. We expect this trend to continue and to affect drug products with even relatively modest revenues.

Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will prevail in our enforcement or defense of our patent rights. Our existing patents could be invalidated, found unenforceable, or found not to cover a generic form of our product.

Failure to obtain or maintain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business.

We intend to sell certain of our products, outside the United States and recently received market authorization under the mutual recognition procedure to sell BioThrax, in France, Italy, the Netherlands, Poland, and the U.K. To market our products in foreign jurisdictions under normal circumstances, we may need to obtain separate regulatory approvals and comply with numerous and varying requirements or use alternative "emergency use" or other exemptions from general approval and import requirements. Approval by the FDA in the United States or the mutual recognition procedure in the European member states does not ensure approval by all foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review beyond that required by the FDA or under the mutual recognition procedure. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and we may be unable to successfully commercialize our products internationally if no alternate procurement pathway is identified for authorized government customers in a particular jurisdiction. We have limited experience in preparing, filing and prosecuting the applications necessary to gain foreign regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

Our international operations increase our risk of exposure to potential claims of bribery and corruption.

As we continue to expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act (the "FCPA"), the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, or other similar foreign laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices are found to be in violation of the FCPA or similar foreign laws despite our training and compliance efforts, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, operating results, cash flows and growth prospects.

The expansion of our international operations increases our risk of exposure to credit losses.

As we continue to expand our business activities with foreign governments in certain countries that have experienced deterioration in credit and economic conditions or otherwise, our exposure to uncollectible accounts will rise. Global economic conditions and liquidity issues in certain countries have resulted and may continue to result in delays in the collection of accounts receivables and may result in credit losses. Future governmental actions and customer specific actions may require us to re-evaluate the collectability of our accounts receivable and we may potentially incur credit losses that may materially impact our operating results.

MANUFACTURING RISKS

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax or our other products, as well as deliver our contract development and manufacturing services, which would harm our business, financial condition, operating results and cash flows.

An interruption in our manufacturing operations could result in our inability to produce our PHT countermeasures for delivery to satisfy the product demands of our customers in a timely manner, which would reduce our revenues and materially harm our business, financial condition, operating results and cash flows. A number of factors could cause interruptions, including:

- § equipment malfunctions or failures;
- § technology malfunctions;
- § cyber-attacks;
- § work stoppages or slow-downs;
- § protests, including by animal rights activists;
- § injunctions;
- § damage to or destruction of the facility; and
- § product contamination or tampering.

Providers of PHT countermeasures could be subject to an increased risk of terrorist activities. The USG has designated both our Lansing, Michigan and our Bayview bulk manufacturing facility in Baltimore, Maryland as facilities requiring additional security. Although we continually evaluate and update security measures, there can be no assurance that any additional security measures would protect these facilities from terrorist efforts determined to disrupt our manufacturing activities.

The factors listed above could also cause disruptions at our other facilities, including our manufacturing facilities in Winnipeg, Manitoba, Canada; other Baltimore, Maryland facilities in Camden; facilities in Canton, Massachusetts; Rockville, Maryland; and Hattiesburg, Mississippi. We do not have any redundant manufacturing facilities for any of our marketed products. Accordingly, any disruption, damage, or destruction of these facilities could impede our ability to manufacture our marketed products, our product candidates and our ability to produce products for external customers, result in losses and delays, including delay in the performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and materially harm our business, financial condition, operating results and cash flows.

We may not be able to utilize the full manufacturing capacity of our manufacturing facilities, which could impact our future revenues and materially harm our business, financial condition, operating results and cash flows.

Despite our ongoing efforts to optimize the utilization of our manufacturing infrastructure (including bulk, fill/finish, support, aseptic filling, lyophilization, final packaging), we may not be able to realize full utilization, which could adversely affect our future revenues, financial condition, operating results and cash flows.

Problems may arise during the production of our marketed products and product candidates due to the complexity of the processes involved in their manufacturing and shipment. Significant delays in product manufacturing or development could cause delays in revenues, which would harm our business, financial condition, operating results and cash flows.

BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT, VIGIV, Vivotif, Vaxchora, and many of our current product candidates, including NuThrax, are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. Problems during manufacturing may arise for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other quality control testing, may result in lot failures or manufacturing shut-downs, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, as our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-downs, delay in the release of lots, product recalls, spoilage or regulatory action. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us, including warning letters and other restrictions on the marketing or manufacturing of a product, or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us, damage our reputation and negatively impact our business.

We are contractually required to ship our biologic products at a prescribed temperature range and variations from that temperature range could result in loss of product and could significantly and adversely impact our revenues, which would harm our business, financial condition, operating results and cash flows.

Manufacturing delays, lot failures, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in potential clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

We are required to obtain FDA approval prior to the release of each lot of BioThrax and ACAM2000, which may not be obtained on a timely basis or at all.

FDA approval is required for the release of each lot of BioThrax and ACAM2000. We are not able to sell any lots that fail to satisfy the release testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before lots are released for sale. Potency testing of each lot of BioThrax and each lot of ACAM2000 is performed against qualified control lots that we maintain. We continually monitor the status of our reference lots and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are not able to produce and qualify a new reference lot or otherwise satisfy the FDA's requirements for release of BioThrax or ACAM2000, our ability to sell BioThrax or ACAM2000 would be impaired until such time as we become able to meet the FDA's requirements, which would materially harm our business, financial condition, operating results and cash flows.

If we are unable to obtain supplies for the manufacture of our products and product candidates in sufficient quantities, at an acceptable cost and in acceptable quality, our ability to manufacture or to develop and commercialize our products and product candidates could be impaired, which could materially harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise materially harm our business.

We depend on certain single-source suppliers for key materials and services necessary for the manufacture of BioThrax and our other products and product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture BioThrax and NuThrax, and currently rely on a single-source supplier to manufacture raxibacumab. We also rely on single-source suppliers for the sponge applicator device and the active ingredient used to make RSDL as well as the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for ACAM2000. A disruption in the availability of such materials or services from these suppliers or in the quality of the material provided by such suppliers could require us to qualify and validate alternative suppliers. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us and otherwise materially harm our business, financial condition, operating results and cash flows.

Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, bacteria and viruses, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with and be inspected by the CDC and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer, select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities

and personnel and establishes a comprehensive national database of registered entities. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. From time to time, we have been involved in remediation activities and may be so involved in the future. Any related cost or liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business, financial condition, operating results and cash flows. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U.S. Department of Agriculture and the DoD, as well as regulatory authorities in Canada.

RISKS RELATED TO STRATEGIC ACQUISITIONS AND COLLABORATIONS

Our strategy of generating growth through acquisitions may not be successful.

Our business strategy includes growing our business through acquisition and in-licensing transactions. We may not be successful in identifying, effectively evaluating, structuring, acquiring or in-licensing, and developing and commercializing additional products on favorable terms, or at all. Competition for attractive product opportunities is intense and may require us to devote substantial resources, both managerial and financial, to an acquisition opportunity. A number of more established companies are also pursuing strategies to acquire or in-license products in the biopharmaceutical field. These companies may have a competitive advantage over us due to their size, cash resources, cost of capital, effective tax rate and greater clinical development and commercialization capabilities.

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant resources to potential acquisitions that are never completed. Even if we are successful in acquiring a company or product, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial, and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities.

If we are unsuccessful in our efforts to acquire other companies or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business, and we could be compelled to record significant impairment charges to write-down the carrying value of our acquired intangible assets, which could materially harm our, business, financial condition, operating results and cash flows.

Our failure to successfully integrate acquired businesses and/or assets into our operations could adversely affect our ability to realize the benefits of such acquisitions and, therefore, to grow our business.

We may not be able to integrate any acquired business successfully or operate any acquired business profitably, including our recent acquisitions of Adapt and PaxVax. In addition, cost synergies, if achieved at all, may be less than we expect, or may take greater time to achieve than we anticipate.

Issues that could delay or prevent successful integration or cost synergies of an acquired business or products include, among others:

- § retaining existing customers and attracting new customers;
- § retaining key employees;
- § diversion of management attention and resources;
- § conforming internal controls, policies and procedures, business cultures and compensation programs;
- § consolidating corporate and administrative infrastructures;
- § successfully executing technology transfers and obtaining required regulatory approvals;
- § consolidating sales and marketing operations;
- § identifying and eliminating redundant and underperforming operations and assets;
- § assumption of known and unknown liabilities;
- § coordinating geographically dispersed organizations; and
- § managing tax costs or inefficiencies associated with integrating operations.

If we are unable to successfully integrate pending and future acquisitions with our existing businesses, or operate any acquired business profitably, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect the growth of our business, financial condition, operating results and cash flows.

COMPETITIVE AND POLITICAL RISKS

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

The development and commercialization of new biopharmaceutical and medical technology products is highly competitive and subject to rapid technological advances. We may face future competition from other companies and governments, universities and other non-profit research organizations in respect to our products, any products that we acquire, our current product candidates and any products we may seek to develop or commercialize in the future. Our competitors may develop products that are safer, more effective, more convenient or less costly than any products that we may develop or market. Our competitors may have greater resources to devote to marketing or selling their products, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully than we can, or more effectively negotiate third-party licensing and collaborative arrangements.

There are a number of companies with products or product candidates addressing PHT preparedness that are competing with us for both USG procurement and development resources. Many of our competitors have greater financial, technical and marketing resources than we do. Our competitors may receive patent protection that dominates, blocks or adversely affects our products or product candidates.

Any reduction in demand for our products or reduction or loss of development funding for our products or product candidates in favor of a competing product could lead to a loss of market share for our products and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows.

Our Biologic Products may face risks of competition from biosimilar manufacturers.

Competition for BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT, VIGIV, Vivotif and Vaxchora otherwise referred to as our "Biologic Products," may be affected by follow-on biologics, or "biosimilars," in the United States and other jurisdictions. Regulatory and legislative activity in the United States and other countries may make it easier for generic drug manufacturers to manufacture and sell biological drugs similar or identical to our Biologic Products, which might affect the profitability or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve a biosimilar application until the 12-year exclusivity period for the innovator biologic has expired. Regulators in the European Union and in other foreign jurisdictions have already approved biosimilars. The specific regulatory framework for this biosimilar approval path and the extent to which an approved biosimilar would be substituted for the innovator biologic are not yet clear and will depend on many factors. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business, financial condition, operating results and cash flows.

We expect our recently acquired NARCAN® Nasal Spray marketed product to face future competition from other treatments.

Our marketed product NARCAN® Nasal Spray faces substantial competition from other treatments, including injectable naloxone, auto-injectors and improvised nasal kits. In addition, other entrants may seek approval to market generic versions of NARCAN® Nasal Spray before the underlying patents

expire. For example, in 2016 Teva filed, and in 2018 Perrigo filed, ANDAs which seek regulatory approval to market generic versions of NARCAN® Nasal Spray before the expiration of certain underlying patents. Additionally, in January 2019, the FDA released new proposed template Drug Facts Labels to assist sponsors of investigation naloxone nasal sprays and auto-injectors seeking approval from the FDA for over-the-counter naloxone products. Any reduction in demand for NARCAN® Nasal Spray in favor of a competing product, or unsuccessful efforts to defend underlying patents from infringement by generic entrants, could lead to a loss of market share and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows.

Political or social factors may delay or impair our ability to market our products and may require us to spend significant management time and financial resources to address these issues.

Products developed to counter the potential impact of PHTs, whether CBRNE or EID, are subject to changing political and social environments. The political responses and social awareness of the risks of these threats on military personnel or civilians may vary over time. If the threat of terrorism were to decline, then the public perception of the risk on public health and safety may be reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products in development to market or limit pricing or purchases of our products, any of which could negatively affect our revenues and our business, financial condition, operating results and cash flows.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Lawsuits brought against us by third parties or activists, even if not successful, could require us to spend significant management time and financial resources defending the related litigation and could potentially damage the public's perception of us and our products. Any publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of our PHT countermeasures and thereby limit the demand for our products, which would adversely affect our business, financial condition, operating results and cash flows.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

Our growth depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business would be materially and adversely affected.

We have invested significant effort and financial resources in the development of our vaccines, therapeutics and medical device product candidates and the acquisition of additional product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the USG's interest in providing development funding for or procuring certain of our product candidates, and the commercial viability of our acquired or developed product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

- successful development, formulation and cGMP scale-up of manufacturing that meets FDA or other foreign regulatory requirements;
- successful program partnering;
- successful completion of clinical or non-clinical development, including toxicology studies and studies in approved animal models;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing processes and product supply arrangements;
- training of a commercial sales force for the product, whether alone or in collaboration with others;
- successful registration and maintenance of relevant patent and/or other proprietary protection; and
- acceptance of the product by potential government and other customers.

Under certain circumstances, we might sell unapproved MCMs to government entities. While this is permissible in some cases, the extent to which we may be able to lawfully market and sell unapproved products in many jurisdictions may be unclear or ambiguous. Such sales could subject us to regulatory enforcement action, product liability and reputational risk.

Under certain circumstances, MCMs may be procured by government entities prior to approval by the FDA or other regulatory authorities. In the United States, Project BioShield permits the Secretary of HHS to contract to purchase MCMs for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 also allow the FDA Commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an EUA pre-approval. Absent an applicable exception, our MCM product candidates generally will have to be approved by the FDA or other regulatory authorities through traditional pathways before we can sell those products to governments. Additionally, the laws in certain jurisdictions regarding the ability of government entities to purchase unapproved product candidates are ambiguous, and the permissibility of exporting unapproved products from the United States and importing them to foreign countries may be unclear. Nevertheless, government bodies, such as U.S. federal entities other than HHS, state and local governments within the United States, and foreign governments, may seek to procure our MCM product candidates that are not yet approved. If so, we would expect to assess the permissibility and liability implications of marketing our product candidates to such entities on a case-by-case basis, which presents certain challenges, both in the case of U.S. and foreign governments, and particularly under emergency conditions. In addition, agencies or branches of one country’s government may take different positions regarding the permissibility of such sales than another country’s government or even other agencies or branches of the same government. If we determine that we believe such activities are permissible, local enforcement authorities could disagree with our conclusion and take enforcement action against us.

In addition, the sale of unapproved products also could give rise to product liability claims for which we may not be able to obtain indemnification or insurance coverage. For example, liability protections applicable to claims arising under U.S. law and resulting from the use of certain unlicensed products, such as a declaration issued under the PREP Act may not cover claims arising under non-U.S. law.

Regardless of the permissibility and liability risks, in the event a user of one or more of our products suffers an adverse event, we may be subject to additional reputational risk if the product has not been approved by the FDA or the corresponding regulatory authority of another country particularly because we will not have approved labeling regarding the safety or efficacy of those products. In addition, legislatures and other governmental bodies that have oversight responsibility for procuring agencies may raise concerns after the fact even if procurement was permissible at the time, which could result in negative publicity, reputational risk and harm to our business prospects.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products. Failure to obtain regulatory approval for product candidates, particularly in the United States, could materially and adversely affect our financial resources, which would adversely affect our business, financial condition, operating results and cash flows.

Before obtaining regulatory approval for the marketing of our product candidates, we and our collaborative partners, where applicable, must conduct preclinical studies and clinical trials to establish proof of concept and demonstrate the safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

For certain of our product candidates addressing CBRNE threats, we expect to rely on the Animal Rule to obtain regulatory approval. The Animal Rule permits, in certain limited circumstances, the use of animal efficacy studies, together with human clinical safety and immunogenicity trials, to support an application for marketing approval. For a product approved under the Animal Rule, certain additional post-marketing requirements apply. For example, to the extent feasible and ethical, applicants must conduct post-marketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated. We have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our product candidates in humans.

Under Project BioShield, the Secretary of HHS can contract to purchase MCMs for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the FDA commissioner to authorize the emergency use of medical products that have not yet been

approved by the FDA under an Emergency Use Authorization. If our product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms for distribution in the United States.

We may experience unforeseen events or issues during, or as a result of, preclinical testing, clinical trials or animal efficacy studies. These issues and events, which could delay or prevent our ability to receive regulatory approval for a product candidate, include, among others:

- § our inability to manufacture sufficient quantities of materials for use in trials;
- § the unavailability or variability in the number and types of subjects for each study;
- § safety issues or inconclusive or incomplete testing, trial or study results;
- § drug immunogenicity;
- § lack of efficacy of product candidates during the trials;
- § government or regulatory restrictions or delays; and
- § greater than anticipated costs of trials.

We depend on third parties to conduct our clinical and non-clinical trials. If these third parties do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and, as a result, our business, financial condition, operating results and cash flows may suffer.

We do not have the ability to independently conduct the clinical and non-clinical trials required to obtain regulatory approval for our product candidates. We depend on third parties, such as independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with good clinical practice regulations and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

In certain cases, government entities and non-government organizations conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. Furthermore, government entities depend on annual Congressional appropriations to fund their development efforts, which may not be approved.

If we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

We continue to evaluate our product development strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. We may change or refocus our existing product development, commercialization and manufacturing activities based on government funding decisions. This could require changes in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates or choose candidates for which government development funds are not available. Our decisions to allocate our research and development, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better business opportunities. Similarly, our decisions to delay or terminate product development programs may also prove to be incorrect and could cause us to miss valuable opportunities.

INTELLECTUAL PROPERTY RISKS

If we are unable to protect our proprietary rights, our business, financial condition, operating results, and cash flows could be materially harmed.

Our success will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property incorporated into or covering our technology, products, and product candidates. Obtaining and maintaining protection of our intellectual property is very costly. The patentability of technology in the biopharmaceutical field generally is highly uncertain and involves complex legal and scientific questions.

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may inadvertently lapse or be challenged, narrowed, invalidated, or circumvented, and such happenings could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our products. In the past, we have abandoned the prosecution and/or maintenance of patent applications related to patent families in the ordinary course of business. In the future we may choose to abandon such prosecution and/or maintenance in a similar fashion. If these patent rights are later determined to be valuable or necessary to our business, our competitive position may be adversely affected. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and in other countries may diminish the value of our intellectual property, narrow the scope of our patent protection, or result in costly defensive measures. In addition, some countries do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our products or product candidates.

The cost of litigation to uphold the validity of patents to prevent or stop infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents may be subjected to opposition proceedings or validity challenges. Some of our competitors may choose to or be better able to sustain the costs of complex patent litigation. Intellectual property lawsuits are expensive and unpredictable and consume management's time and attention and other resources, even if the outcome is successful. In addition, there is a risk that a court could decide that our patents are not valid, are unenforceable, or are not infringed by a competitor product. There is also a risk that, even if the validity of a patent is upheld, a court could refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events occur, our business, financial condition, operating results and cash flows could be materially and adversely affected.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend intellectual property rights that we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license from:

- · Pfizer, Inc. an oligonucleotide adjuvant, CPG 7909, for use in our NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant) anthrax vaccine product candidate.
- · Opiant Pharmaceuticals, Inc. formulations of naloxone, for use in our NARCAN® Nasal Spray.
- · Pharma Consult GmbH autoinjectors, including the autoinjector used for our Trobigard® (atropine sulfate, obidoxime chloride) autoinjector.*

**Trobigard® is not currently approved or cleared by the FDA or any similar regulatory body and is only distributed to authorized government buyers for use outside the US. This product is not distributed in the US.*

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to market and sell our products, and therefore our business, financial condition, operating results, and cash flows could be materially and adversely affected.

Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations could be costly, time-consuming, distracting to management, and could materially and adversely affect our business, financial condition, operating results, and cash flows.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties for which we do not hold sufficient licenses or other rights. Additionally, third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. Third parties may own or control these patents and intellectual property rights in the United States and abroad. These third parties could bring claims against us that could cause us to incur substantial expenses to defend against these claims and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement or other similar suit is brought against us, we could be forced to stop or delay development, manufacturing, or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the biopharmaceutical industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations. If, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, if at all, or if an injunction is granted against us, these could materially harm our business, financial condition, operating results, and cash flows.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license and/or sue us for breach, which could cause us to not be able to market any product that is covered by the license and subject us to damages, which may be material.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We also rely upon unpatented proprietary technology, processes, and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for all of our current products, our only other intellectual property protection for products, other than trademarks, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes, and unique starting materials. However, these types of confidential information and trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants, and third parties, as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information.

These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known, including through a potential cyber security breach, or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, or if others independently develop our proprietary information or processes, competitors may be able to use this information to develop products that compete with our products, which could materially and adversely impact our business.

FINANCIAL RISKS

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our operations to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

- § requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- § increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase;
- § subjecting us, as under our senior secured credit facilities, to restrictive covenants that may reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- § requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- § limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- § placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our debt instruments could result in an event of default under those instruments. An event of default could result in the acceleration of amounts due under a particular debt instrument and a cross default and acceleration under other debt instruments, and we may not have sufficient funds or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests in our assets securing our indebtedness.

Our current indebtedness and any additional debt financing may restrict the operation of our business and limit the cash available for investment in our business operations.

In connection with the acquisition of Adapt, we entered into an amendment and restatement of our 2017 credit agreement to provide for new five-year syndicated senior secured credit facilities that replaced our existing facility. The senior secured credit facilities include a $450 million Term Loan and the ability to borrow up to a $600 million revolver, of which we have drawn down $450 million and $318 million, respectively. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

- § the level, timing and cost of product sales and contract manufacturing services;
- § the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- § the acquisition of new facilities and capital improvements to new or existing facilities;
- § the payment obligations under our indebtedness;
- § the scope, progress, results and costs of our development activities;
- § our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- § the extent to which we repurchase additional common stock under our authorized share repurchase program; and
- § the costs of commercialization activities, including product marketing, sales and distribution.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our debt instruments could result in an event of default under those instruments. An event of default could result in the acceleration of amounts due under a particular debt instrument and a cross default and acceleration under other debt instruments, and we may not have sufficient funds or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests in our assets securing our indebtedness.

We may require significant additional funding and may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, and our results of operations and financial condition.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. In August 2018, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules (which include, among other things, the timely filing of our reports under the Exchange Act and maintenance of at least $700 million of public float or issuing an aggregate amount of $1 billion of non-convertible securities, other than common stock, in registered offerings for cash during the past three years), this shelf registration statement, effective until August 8, 2021, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we do not file a new shelf registration statement prior to August 8, 2021, the existing shelf registration statement will expire, and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured credit facilities, limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us. We are not restricted under the terms of the indenture governing our 2.875% Convertible Senior Notes due 2021 ("Senior Convertible Notes") from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that could have the effect of diminishing our ability to make payments on our indebtedness. However, our senior secured credit facilities restrict our ability to incur additional indebtedness, including secured indebtedness.

Economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, operating results, financial condition and cash flows would be adversely affected, and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

We may not maintain profitability in future periods or on a consistent basis.

Although we have been profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. For example, we incurred a net loss in the second quarter of 2016 and in each of the first quarters of 2018, 2015, 2014 and 2013. Our profitability has been substantially dependent on BioThrax product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the USG. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

THE SPIN-OFF OF OUR BIOSCIENCES BUSINESS

If the spin-off distribution on August 1, 2016 of all of the outstanding shares of Aptevo Therapeutics Inc. common stock to our stockholders does not qualify as a tax-free transaction for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.

It was our intention that our distribution on August 1, 2016 of all of the outstanding shares of Aptevo common stock to our stockholders (the "Distribution"), together with certain related transactions, qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended (the "Code"). In anticipation of the Distribution, we received a favorable private letter ruling from the Internal Revenue Service (the "IRS"), regarding certain U.S. federal income tax matters relating to the Distribution and certain related transactions and an opinion of counsel substantially to the effect that, for U.S. federal income tax purposes, the Distribution, together with certain related transactions, will qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code. A "private letter ruling," is a written statement issued to a taxpayer by an Associate Chief Counsel Office of the Office of Chief Counsel that interprets and applies the tax laws to a specific set of facts. Our private letter ruling is based on certain facts and representations submitted by us to the IRS and the opinion of counsel was based upon and relied on, among other things, the IRS private letter ruling and certain facts and assumptions, as well as certain representations and covenants of us and Aptevo contained in a tax matters agreement and certain representations contained in representation letters provided by us, Aptevo and certain stockholders to such counsel, including representations and covenants relating to the past and future conduct of us, Aptevo and such stockholders. If any of these facts, assumptions, representations, or covenants are, or become, inaccurate or incomplete, the IRS private letter ruling and/or the opinion of counsel may be invalid and the conclusions reached therein could be jeopardized and, as a result, the Distribution, together with certain related transactions, could fail to qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code for U.S. federal income tax purposes.

In addition, the IRS private letter ruling only addresses certain limited matters relevant to determining whether the Distribution, together with certain related transactions, qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, and the opinion of counsel only represents the judgment of such counsel, which is not binding on the IRS or any court. Accordingly, notwithstanding the IRS private letter ruling and the opinion of counsel, there can be no assurance that the IRS will not assert that the Distribution, together with certain related transactions, should be treated as a taxable transaction for U.S. federal income tax purposes or that a court would not sustain such a challenge.

If the Distribution, together with certain related transactions, fails to qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, in general, (i) we would recognize taxable gain on the Distribution equal to the amount by which the fair market value of the Aptevo shares distributed to our stockholders exceeded our tax basis in the Aptevo shares and (ii) each of our stockholders who received Aptevo shares in the Distribution would be treated as receiving a taxable distribution equal to the fair market value of the Aptevo shares received by such stockholder.

Under the tax matters agreement that we entered into with Aptevo in connection with the spin-off, Aptevo may be required to indemnify us against any tax liabilities and related expenses resulting from the failure of the Distribution, together with certain related transactions, to qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Aptevo's stock, assets or business, or a breach of the relevant representations or covenants made by Aptevo in the tax matters agreement or the IRS private letter ruling or in the representation letters provided to our counsel for purposes of their opinion. Any such indemnity obligations could be material, and there can be no assurance that Aptevo will be able to pay any such indemnification.

To preserve the tax-free treatment of the Distribution, together with certain related transactions, and in addition to Aptevo's indemnity obligation, the tax matters agreement, which expired on August 2, 2018, restricted Aptevo from taking any action that prevents such transactions from being tax-free for U.S. federal income tax purposes. In particular, for the two-year period following the Distribution, Aptevo was restricted from taking certain actions (including restrictions on share issuances, business combinations, sales of assets, amendments to organizational documents and similar transactions) that could cause the Distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. There can be no assurance that Aptevo adequately complied with these restrictions. If a finding is made by the IRS through a tax audit that Aptevo failed to satisfy its obligations, this could have a substantial impact on our tax obligations, consolidated financial condition and cash flows.

In connection with Aptevo's separation from us, Aptevo agreed to indemnify us for certain matters. This indemnity may not be sufficient to hold us harmless from the full amount of losses that we may incur in connection with these matters, and Aptevo may not be able to satisfy its indemnification obligations to us.

Pursuant to the agreements that we entered into with Aptevo at the time of Aptevo's separation from us, Aptevo agreed to indemnify us for certain matters, including liabilities related to Aptevo's business or for which Aptevo otherwise agreed to be responsible in the separation. This indemnity from Aptevo may not be sufficient to protect us against the full amount of losses that we may incur in connection with these matters, including if third parties assert claims against us for liabilities that were allocated to Aptevo in the separation. Moreover, Aptevo may dispute its indemnification obligation to us or have insufficient resources to satisfy its indemnification obligations to us. Even if we ultimately succeed in recovering from Aptevo the amount of any losses that we incur in connection with these matters, the recovery could take a substantial amount of time and we may be required to bear these losses ourselves while we seek recovery. Each of these risks could negatively affect our business, operating results, financial condition and cash flows.

OTHER BUSINESS RISKS

We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations.

We face an inherent risk of product liability exposure related to the sale of our products, any other products that we successfully acquire or develop and the testing of our product candidates in clinical trials.

One measure of protection against such lawsuits is coverage under the PREP Act, which was signed into law in December 2005. The PREP Act creates liability protection for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide liability protection from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations identifying certain of our products, namely BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT and VIGIV, as covered countermeasures. These declarations expire in 2022. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates.

Additionally, certain of our products, namely BioThrax and RSDL, are certified anti-terrorism products covered under the protections of the SAFETY Act. The SAFETY Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although we are entitled to the benefits of the SAFETY Act for BioThrax and RSDL, the SAFETY Act may not provide adequate protection from claims made against us.

If we cannot successfully defend ourselves against future claims that our products or product candidates caused injuries and if we are not entitled to indemnity by the USG does not honor its obligations to us under the PREP Act or SAFETY Act, or if the indemnification under the PREP Act and SAFETY Act is not adequate to cover all claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand or withdrawal of a product;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- an inability to commercialize products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large-scale deployment of BioThrax as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT and VIGIV, and SAFETY Act protection for BioThrax and RSDL in addition to our insurance coverage to help mitigate our product liability exposure for these products. Additionally, potential product liability claims related to our commercial products, including NARCAN® Nasal Spray, Vivotif and Vaxchora, may be made by patients, health care providers or others who sell or consume these products. Such claims may be made even with respect to those products that possess regulatory approval for commercial sale. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, operating results and cash flows.

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. A material weakness in our internal control over financial reporting could have an adverse effect on our business and financial results and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our common stock.

Internal control over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements and may not prevent or detect misstatements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Failure to maintain effective internal control over financial reporting, or lapses in disclosure controls and procedures, could impact our financial information and disclosures, require significant resources to remediate, and expose us to legal or regulatory proceedings.

We regularly review and update our internal controls and disclosure controls and procedures. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Our system of internal controls, however well-designed, can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting, or the internal controls of other companies we may acquire, are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial reporting, and the trading price of our common stock could be negatively affected.

We rely significantly on information technology systems and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively or result in data leakage of proprietary and confidential business and employee information.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employee error, malfeasance or other disruption—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property or could lead to the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others.

A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to our proprietary and confidential business and employee information could result in financial, legal, business or reputational harm to us, any of which could materially and adversely affect our business, financial condition and operating results.

Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. If we are unable to retain the services of one or more of the principal members of senior management or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package to attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

Fuad El-Hibri, executive chairman of our Board of Directors, has significant influence over us through his substantial beneficial ownership of our common stock, including an ability to influence the election of the members of our Board of Directors, or delay or prevent a change of control of us.

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of February 15, 2019, Mr. El-Hibri was the beneficial owner of approximately 11% of our outstanding common stock. As a result, Mr. El-Hibri could exercise substantial influence over all corporate actions requiring board or stockholder approval, including a change of control, or any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions. In addition, Mr. El-Hibri's significant beneficial ownership of our shares could present the potential for a conflict of interest.

Provisions in our certificate of incorporation and by-laws and under Delaware law may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

Provisions in our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management.

These provisions include:

- § the classification of our directors;
- § limitations on changing the number of directors then in office;
- § limitations on the removal of directors;
- § limitations on filling vacancies on the board;
- § advance notice requirements for stockholder nominations of candidates for election to the Board of Directors and other proposals;
- § the inability of stockholders to act by written consent;
- § the inability of stockholders to call special meetings; and
- § the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

The affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. The affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, we are subject to Section 203 of the Delaware General Corporation Law ("Section 203"). In general and subject to certain exceptions, Section 203 prohibits a publicly-held corporation from engaging in a business combination with an interested stockholder, generally a person which, together with its affiliates, owns or within the last three years has owned 15% or more of the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

Our Board of Directors may implement a new stockholder rights plan without stockholder approval, which could prevent a change in control of us in instances in which some stockholders may believe a change in control is in their best interests.

Our Board of Directors may implement a stockholder rights plan without stockholder approval. We previously implemented a stockholder rights plan, which expired on November 14, 2016. Under our prior stockholder rights plan, we issued to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, would have entitled its holder to purchase from us a unit consisting of one one-thousandth of a share of series A junior participating preferred stock at a purchase price of $150 in cash, subject to adjustments. Our stockholder rights plan was intended to protect stockholders in the event of an unfair or coercive offer to acquire us and to provide our Board of Directors with adequate time to evaluate unsolicited offers.

Our Board of Directors may implement a new stockholder rights plan, which may have anti-takeover effects, potentially preventing a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. This could cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests or those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

Our stock price is volatile and purchasers of our common stock could incur substantial losses.

Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this "Risk Factors" section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through February 15, 2019, our common stock has traded as high as $73.89 per share and as low as $4.40 per share. The stock market in general as well as the market for biopharmaceutical companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including, among others:

- § contracts, decisions and procurement policies by the USG affecting BioThrax and our other products and product candidates;
- § the success of competitive products or technologies;
- § results of clinical and non-clinical trials of our product candidates;
- § announcements of acquisitions, financings or other transactions by us;
- § litigation or legal proceedings;
- § public concern as to the safety of our products;
- § termination or delay of a development program;
- § the recruitment or departure of key personnel;
- § variations in our product revenue and profitability; and
- § the other factors described in this "Risk Factors" section.

Because we currently do not pay dividends, investors will benefit from an investment in our common stock only if it appreciates in value.

We currently do not pay dividends on our common stock. Our senior secured credit facilities limit and any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

A significant portion of our shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6 million shares of our common stock outstanding as of February 15, 2019, have the right to require us to register these shares of common stock under specified circumstances.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We own and lease approximately 1.8 million square feet of building space for manufacturing, laboratories, fill/finish facility services, offices and warehouse space for the conduct of our businesses at 19 locations in North America and Europe. In North America, we own and lease approximately 1.1 million square feet and 0.2 million square feet of building space, respectively, at 17 locations. Leased properties expire on various dates from 2019 to 2027. Principal locations include:

Location	Use	Approximate square feet	Owned/leased
Bern, Switzerland	Manufacturing facilities and office and laboratory space	511,000	Owned
Lansing, Michigan	Manufacturing operations facilities, office space and laboratory space	336,000	Owned
Winnipeg, Manitoba, Canada	Manufacturing operations facilities, office space and laboratory space	315,000	Owned
Gaithersburg, Maryland	Office space and rental real estate	130,000	Owned
Baltimore, Maryland (Bayview)	Manufacturing facilities and office and laboratory space	112,000	Owned

Each property is considered to be in good condition, adequate for its purpose, and suitably utilized according to the individual nature and requirements of the relevant operations. Our policy is to improve and replace property as considered appropriate to meet the needs of the individual operation.

ITEM 3. LEGAL PROCEEDINGS

ANDA Litigation

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd., or collectively, Adapt Pharma, and Opiant Pharmaceuticals, Inc., or Opiant, received notice from Perrigo UK FINCO Limited Partnership, or Perrigo, that Perrigo had filed an Abbreviated New Drug Application, or ANDA, with the United States Food and Drug Administration, or FDA, seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, or the ‘253 Patent, 9,468,747, or the ‘747 Patent, 9,561,177, or the ‘177 Patent, 9,629,965, or the ‘965 Patent, and 9,775,838, or the ‘838 Patent. On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937, or the ‘937 Patent. Perrigo’s notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions’ Adapt Pharma subsidiaries and Opiant, or collectively, Plaintiffs, filed a complaint for patent infringement of the ‘253, ‘747, ‘177, ‘965, and the ‘838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo’s ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the ‘937 Patent. As a result of timely filing the first lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo’s ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the Court.

On or about February 27, 2018, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva Pharmaceuticals Industries Ltd. and Teva Pharmaceuticals USA, Inc., or collectively Teva, that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2 mg/spray before the expiration of U.S. Patent No. 9,480,644, or the ‘644 Patent, and U.S. Patent No. 9,707,226, or the '226 Patent. Teva's notice letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey.

On or about September 13, 2016, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration of U.S. Patent No. 9,211,253, or the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the '747, the '177, the '965, the '838, and the ‘937 Patents. Teva's notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '253, the '747, the '177, the '965, the '838, or the ‘937 Patent, or that the '253, the '747, the '177, the '965, the '838, and the ‘937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings have been consolidated. As of February 21, 2019, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, are evaluating Teva's notice letter related to the ‘937 Patent.

In the complaints described in the paragraphs above, the Plaintiffs seek, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo’s respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court.

Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn (“Sponn”), filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company’s common stock between January 11, 2016 and June 21, 2016, inclusive (the “Class Period”), seeking to pursue remedies under the Exchange Act against the Company and certain of its senior officers and directors (collectively, the “Defendants”). The complaint alleged, among other things, that the Defendants made materially false and misleading statements about the government’s demand for BioThrax and expectations that the Company’s five-year exclusive procurement contract with HHS would be renewed, and omitted certain material facts. Sponn sought unspecified damages, including legal costs. On October 25, 2016, the court added City of Cape Coral Municipal Firefighters’ Retirement Plan and City of Sunrise Police Officers’ Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robbins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Plaintiffs filed an amended complaint that cited the same class period, named the same defendants and made similar allegations to the original complaint. The Defendants filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Defendants’ Motion to Dismiss was heard and denied on July 6, 2017. The Defendants filed an answer on July 28, 2017. The parties then engaged in the process of exchanging discovery. The Plaintiffs filed an amended motion for class certification and appointment of Lead Plaintiffs, Sponn, and Geoffrey L. Flagstad (“Flagstad”) as Class Representatives on December 20, 2017. A hearing on that motion was heard on May 2, 2018. On June 8, 2018 the Court granted class certification with a shortened class period, May 5, 2016 to June 21, 2016. In that same order, the court appointed Flagstad as Class Representative and Robbins Geller Rudman & Dowd LLP as Class Counsel. The Defendants have denied, and continue to deny, any and all allegations of fault, liability, wrongdoing, or damages. However, recognizing the risk, time, and expense of litigating any case to trial, on August 27, 2018, the Defendants reached an agreement in principle with Plaintiffs to settle all of the related claims of any individual plaintiff that purchased or acquired Company stock from January 11, 2016 to June 21, 2016, for $6.5 million, an amount that was paid by the Company’s insurance carrier. The settlement required no payment by any of the Defendants. The Defendants continue to deny any and all liability. The parties executed the settlement agreement on October 16, 2018 and filed the agreement with the court on October 17, 2018. The court granted preliminary approval of the settlement on October 18, 2018, issued an amended preliminary approval of the settlement on October 25, 2018, and scheduled a hearing regarding final approval for January 22, 2019. At the time of the final approval hearing on January 22, 2019, there were no objections to the settlement, but there were two shareholders who had submitted opt-outs so that they could be excluded from the settlement. On January 25, 2019, the court issued an order and final judgment approving the settlement. Although the court has approved the settlement, the court’s decision can be appealed for a period of time. In addition, the shareholders who opted out could try to bring their own claims. The Company, therefore, at this time, cannot predict the results of this lawsuit and possible other legal proceedings with certainty. Defendants continue to believe that the allegations in the complaint are without merit.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information and Holders

Our common stock trades on the New York Stock Exchange under the symbol "EBS".

As of February 15, 2019, the closing price per share of our common stock on the New York Stock Exchange was $66.16 and we had 30 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

We have not declared or paid any cash dividends on our common stock since becoming a publicly traded company in November 2006. We currently have no plans to pay dividends.

Recent Sales of Unregistered Securities

On October 15, 2018, we issued 733,309 shares of common stock in a private placement under Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder, as partial consideration for our acquisition of Adapt based on the volume-weighted average price per share of the Common Stock as reported on the New York Stock Exchange for the ten-trading day period ending two days before closing, or $65.28 per share (an aggregate total of $47.9 million, inclusive of adjustments).

Use of Proceeds

Not applicable.

Purchases of Equity Securities

There were no repurchases of common stock that were made through open market transactions during the three months ended December 31, 2018.

Issuer Purchases of Equity Securities

(in millions, except for per share data) Period	Total number of shares (or units) purchased	Average price paid per share (or unit)(a)	Total number of shares (or units) purchased as part of publicly announced plans or programs(b)	Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs (a) (b)
October 1, 2018 - October 31, 2018	-	$ -	-	$ -
November 1, 2018 - November 30, 2018	-	-	-	-
December 1, 2018 - December 31, 2018	-	-	-	-
Total	-	$ -	-	$ 50.0

(a) The amounts do not give effect to any fees, commissions or other costs associated with repurchases of shares.

(b) Under the stock repurchase program, management was authorized to purchase shares of the Company's common stock, from time to time, through open market purchases or privately negotiated transactions at prevailing prices or pursuant to one or more accelerated stock repurchase agreements or other derivative arrangements as permitted by securities laws and other legal requirements, and subject to stock price, business and market conditions and other factors. In March 2018, our board of directors authorized our management to repurchase from time to time up to an aggregate of up to $50 million of our common stock under a board-approved share repurchase program. The term of the authorization expires on December 31, 2019. Any repurchased shares will be available for use in connection with our stock plans and for other corporate purposes. As of December 31, 2018, we have not made any repurchases under this program. We historically have funded and in the future may fund stock repurchases through a combination of cash on hand and cash generated by operations and our senior secured credit facilities or future financing transactions.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

	Year Ended December 31,				
(in millions, except per share data)	2018	2017	2016	2015	2014
Statements of operations data:					
Revenues:					
Product sales	$ 606.5	$ 421.5	$ 296.3	$ 329.0	$ 281.8
Contract manufacturing	98.9	68.9	49.1	43.0	30.9
Contracts and grants	77.0	70.5	143.4	117.3	91.8
Total revenues	782.4	560.9	488.8	489.3	404.5
Operating expenses:					
Cost of product sales and contract manufacturing	322.3	187.7	126.3	102.1	96.6
Research and development	142.8	97.4	106.9	117.8	103.5
Selling, general & administrative	202.5	142.9	143.1	120.6	108.1
Amortization of intangible assets	25.0	8.6	7.0	7.3	7.1
Total operating expenses	692.6	436.6	383.3	347.8	315.3
Income from operations	89.8	124.3	105.5	141.5	89.2
Other income (expense):					
Interest expense	(9.9)	(6.6)	(7.6)	(6.5)	(8.2)
Other income (expense), net	1.6	0.9	1.3	0.7	3.2
Total other income (expense), net	(8.3)	(5.7)	(6.3)	(5.8)	(5.0)

Income from continuing operations before provision for income taxes	81.5	118.6	99.2	135.7	84.2
Provision for income taxes	18.8	36.0	36.7	44.3	29.9
Net income from continuing operations	62.7	82.6	62.5	91.4	54.3
Net loss from discontinued operations	-	-	(10.7)	(28.5)	(17.6)
Net income	$ 62.7	$ 82.6	$ 51.8	$ 62.9	$ 36.7
Net income per share from continuing operations-basic	$ 1.25	$ 1.98	$ 1.56	$ 2.37	$ 1.45
Net loss per share from discontinued operations-basic	-	-	(0.27)	(0.74)	(0.47)
Net income per share-basic	$ 1.25	$ 1.98	$ 1.29	$ 1.63	$ 0.98
Net income per share from continuing operations-diluted	$ 1.22	$ 1.71	$ 1.35	$ 2.02	$ 1.26
Net loss per share from discontinued operations-diluted	-	-	(0.22)	(0.61)	(0.38)
Net income per share-diluted (1)	$ 1.22	$ 1.71	$ 1.13	$ 1.41	$ 0.88
Weighted average number of shares — basic	50.1	41.8	40.2	38.6	37.3
Weighted average number of shares — diluted	51.4	50.3	49.3	47.3	45.8

	As of December 31,				
(in millions)	**2018**	**2017**	**2016**	**2015**	**2014**
Balance Sheet Data:					
Cash and cash equivalents	$ 112.2	$ 178.3	$ 271.5	$ 308.3	$ 276.8
Working capital	420.4	385.3	404.4	425.9	312.8
Total assets	2,229.4	1,070.2	970.1	931.8	815.6
Total long-term liabilities	1,018.1	57.8	268.1	274.6	281.5
Total stockholders' equity	1,010.9	912.2	596.2	575.0	454.5

(1) See "Earnings per share" footnote for details on calculation.

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 financial statements and the related notes and other financial information included elsewhere in this annual report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report on Form 10-K, including information with respect to our plans and strategy for our business and financing, includes forward-looking statements that involve risks and uncertainties. You should carefully review the "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this annual report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are a global life sciences company focused on providing to civilian and military populations a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring public health threats ("PHTs").

We are focused on the following four distinct public health threat categories: CBRNE; EID; travelers' diseases; and opioids. We have a product portfolio of eleven products (vaccines, antibody therapeutics, and drug-device combination products) that generate a majority of our revenue. We also have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates (vaccines, antibody therapeutics, and drug-device combination products). Finally, we also have a fully-integrated portfolio of contract development and manufacturing services. We continue to pursue acquiring and developing products and solutions that provide an opportunity to serve both government customers and commercial (non-government) customers. Our recently acquired products for opioid overdose and travelers' diseases are further expanding our revenue while also contributing to the diversification of the sources of our revenue expanding the commercial (non-government) component of our business.

Our Vaccines and Anti-infective ("VAI") products are BioThrax, ACAM2000, Vivotif and Vaxchora. Our Devices products are NARCAN® Nasal Spray, RSDL and Trobigard. Our Antibody Therapeutic ("ATB") products are raxibacumab, Anthrasil, BAT and VIGIV. See Item 1 "Overview" in this Annual Report on Form 10-K for an additional discussion of our products.

Revenues

We generate revenues from the sale of our eleven marketed products, the performance of contract development and manufacturing services, and our performance of research and development services under contracts and grants that we receive from the U.S. government ("USG") and others.

The USG is the largest purchaser of our CBRNE products and primarily purchases our products for the SNS, a national repository of medical countermeasures including critical antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical supplies. The USG primarily purchases our products under long-term firm fixed price procurement contracts. BioThrax sales to the USG derive the majority of our historical product sales.

Our travelers' disease products, primarily Vivotif and Vaxchora, are sold to wholesalers and distributors, as well as directly to healthcare practitioners. We sell Vivotif and Vaxchora to private travel clinics, retail pharmacies and integrated hospital networks. Our opioid overdose treatment, NARCAN® Nasal Spray, is sold commercially through physician directed or standing order prescriptions at retail pharmacies.

We also earn revenue from the performance of contract development and manufacturing services for third-parties. Our services include fill/finish activities as well as the production of bulk drug substances on behalf of our customers.

We have received contract and grants funding from the USG and other non-governmental organizations to perform research and development activities related to certain emerging infectious diseases.

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis

Cost of Product Sales and Contract Manufacturing

The primary expenses that we incur to deliver our VAI products and ATB products to our customers and to perform contract manufacturing services for our customers consist of fixed and variable costs. Variable manufacturing costs primarily consist of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing operations, sales-based royalties, shipping and logistics. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were manufactured. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity.

The primary expenses that we incur to deliver our Devices to our customers are the cost per unit of production from our third-party contract manufacturers, costs for materials and personnel-related expenses for direct and indirect manufacturing support staff along with facilities and utilities costs. Other associated expenses include sales-based royalties (which includes fair value adjustments associated with contingent consideration), shipping, and logistics.

We use the same manufacturing facilities and methods of production for our own products as well as for fulfillment of our contract manufacturing contracts. We operate nine manufacturing facilities, five of which perform manufacturing activities for contract manufacturing customers. As a result, management reviews expenses associated with manufacturing our own products as well contract manufacturing contracts on an aggregate basis when analyzing the financial performance of its manufacturing facilities. Our manufacturing process for our own products and our contract manufacturing business includes the production of bulk material and performing "fill finish" work for containment and distribution of biological products. For "fill finish" customers, we receive work in process inventory to be prepared for distribution. When producing bulk material, we procure raw materials, manufacture the product and retain the risk of loss through the manufacturing and review process until delivery.

Research and Development Expenses

We expense research and development costs as incurred. Our research and development expenses consist primarily of:

- personnel-related expenses;
- fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material; and
- costs of materials used in clinical trials and research and development.

In many cases, we plan to seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executives, sales and marketing, business development, government affairs, finance, accounting, information technology, legal, human resource functions and other corporate functions. Other costs include facility costs not otherwise included in cost of product sales and contract manufacturing or research and development expense.

Income Taxes

Under the asset and liability method of income tax accounting, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of assets and liabilities and are measured using the tax rates and laws that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A net deferred tax asset or liability is reported on the balance sheet. Our deferred tax assets include the benefit of credit carryforwards, the anticipated future benefit of net operating losses and other timing differences between the financial reporting and tax basis of assets and liabilities.

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The legislation significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, implementing a territorial tax system and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. The SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. This allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. The Company previously provided a provisional estimate of the effect of the Tax Act in our financial statements in 2017 in the amount of $0.2 million comprising a transition tax of $13.6 million offset by a $13.4 million benefit related to the remeasurement of certain deferred tax assets and liabilities. December 22, 2018 marked the end of the measurement period for purposes of SAB 118. As such, we completed our analysis to determine the effect of the Tax Act and recorded a $0.2 million reduction of the transition tax and an additional $4.5 million benefit on the remeasurement of certain deferred tax assets and liabilities in 2018.

Management believes that the assumptions and estimates related to the provision for income taxes are critical to the Company's results of operations. For the year ended December 31, 2018, income tax expense totaled $18.8 million. For every 1% change in the 2018 effective rate, income tax expense would have changed by approximately $0.8 million.

We have historically incurred net operating losses for income tax purposes in some states and foreign jurisdictions. The amount of the deferred tax assets on our balance sheet reflects our expectations regarding our ability to use our net operating losses and research and development tax credit carryforwards, to offset future taxable income. The applicable tax rules in particular jurisdictions limit our ability to use net operating losses and research and development tax credit carryforwards as a result of ownership changes.

We review our deferred tax assets on an annual basis to assess our ability to realize the benefit from these deferred tax assets. If we determine that it is more likely than not that the amount of our expected future taxable income will not be sufficient to allow us to fully utilize our deferred tax assets, we increase our valuation allowance against deferred tax assets by recording a provision for income taxes on our income statement, which reduces net income or increases net loss for that period and reduces our deferred tax assets on our balance sheet. If we determine that the amount of our expected future taxable income will allow us to utilize net operating losses in excess of our net deferred tax assets, we reduce our valuation allowance by recording a benefit from income taxes on our income statement, which increases net income or reduces net loss for that period and increases our deferred tax assets on our balance sheet.

Uncertainty in income taxes is accounted for using a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position.

Results of Operations

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Revenue

	Year ended December 31,			
(in millions)	**2018**	**2017**	**$ Change**	**% Change**

Product sales:				
BioThrax	$ 278.0	$ 286.6	$ (8.6)	(3%)
ACAM2000	116.7	11.5	105.2	915%
Other	211.8	123.4	88.4	72%
Total product sales	606.5	421.5	185.0	44%
Contract manufacturing	98.9	68.9	30.0	44%
Contracts and grants	77.0	70.5	6.5	9%
Total revenues	$ 782.4	$ 560.9	$ 221.5	39%

Product sales:

Substantially all of our sales of BioThrax are made to the USG under long-term procurement contracts at a consistent value per dose. The fluctuations in BioThrax revenue are related to changes in volume depending on when the USG requests delivery. The USG retains a level of BioThrax, as it deems necessary. The price per unit of BioThrax sold was consistent year over year and as such the change in revenue is due to a variance in the number of units sold and the overall long-term contract value remains consistent with prior periods.

ACAM2000 was acquired in October 2017 and as such the increase is due to a full year of results in 2018 compared to a partial year in 2017. Similar to BioThrax, ACAM2000 is sold over a long-term contract requiring delivery to the SNS as ordered.

The increase in other product sales relates primarily to the contribution of recently acquired products which resulted in a $96.0 million increase in other product sales for 2018. Recently acquired products include:

- raxibacumab, acquired in October 2017;
- NARCAN® Nasal Spray, acquired in October 2018;
- Vivotif, acquired in October 2018; and
- Vaxchora; acquired in October 2018.

Contract manufacturing:

The increase in Contract manufacturing revenue is primarily due to:

- fill/finish services provided to third parties;
- the design, construction and validation of manufacturing capability for a third party at our Lansing, Michigan site; and
- manufacturing services performed at our Canton, Massachusetts facility.

Contracts and grants:

The revenues within our Contracts and grants revenues are primarily related to our cost-plus fixed fee contracts with the USG. The increase in Contracts and grants revenues was primarily due to an increase in R&D activities related to ACAM2000 (acquired October 2017), which were conducted pursuant to an existing multi-year development contract with BARDA. R&D activities vary as completed projects end and new projects begin. Excluding the impact of acquisitions, contract and grant revenue was consistent with prior years.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $134.6 million, or 72%, to $322.3 million for 2018 from $187.7 million for 2017. The increase was primarily attributable to our acquired products ACAM2000 and raxibacumab (both acquired October 2017), as well as NARCAN® Nasal Spray, Vivotif and Vaxchora (acquired October 2018).

We have reclassified amortization of intangible assets for the years ended December 31, 2017 and 2016 from cost of product sales and contract manufacturing to amortization of intangible assets to conform to the current period presentation on our consolidated statements of operations.

Research and Development Expenses

Research and development expenses increased by $45.4 million, or 47%, to $142.8 million for 2018 from $97.4 million for 2017. This increase was due primarily to higher contract development services costs. Manufacturing development activities of $25.3 million was attributable to our recently acquired product candidates. Excluding our acquired product candidates, the increase in research and development expense was primarily attributable to:

- manufacturing development activities related to our NuThrax product candidate;
- timing of a Phase 2 clinical study and related activities for our FLU-IGIV (NP025) program; and
- timing of manufacturing development activities and toxicology/safety studies for our SIAN product candidate.

We seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. This funding lowers our overall financial exposure for certain development programs. Management reviews our research and development expenses net of contracts and grants revenues to assess increases in investment spending. During the years ended December 31, 2018 and 2017, we incurred net research and development expenses of $65.8 million and $27.0 million, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $59.6 million, or 42%, to $202.5 million for 2018 from $142.9 million for 2017. The increase was primarily attributable to an increase in acquisition-related costs (transaction and integration) of $21.8 million, expenses associated with the operations from PaxVax and Adapt (both acquired in October 2018) of $19.8 million and an increase in compensation related costs.

Amortization of Intangible Assets

Amortization of intangible assets increased by $16.4 million to $25.0 million for 2018 from $8.6 million for 2017. The increase was entirely due to the acquisitions of PaxVax and Adapt in October 2018 and ACAM2000 and raxibacumab in October of 2017.

Total Other Income (Expense), Net

Total other income (expense), net increased by $2.6 million, or 46%, to $8.3 million for 2018 from $5.7 million for 2017. The increase was primarily attributable to an increase in interest expense due to borrowings to fund our acquisitions of PaxVax and Adapt in October 2018.

Income Taxes

Provision for income taxes decreased by $17.2 million, or 48%, to $18.8 million for 2018 from $36.0 million for 2017. The income tax expense for the years ended December 31, 2018 and 2017 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. During the years ended December 31, 2018 and 2017, the effective rate was 23% and 30%, respectively. During 2018, the Company recognized a $4.7 million benefit relating to adjustments to provisional amounts under SAB 118. The tax benefit was fully offset by the impact of acquisition transaction costs of $5.4 million. The decrease in the effective tax rate during 2018 was primarily attributable to the decrease to the U.S. statutory rate from 35% to 21%, partially offset by the

repeal of the Domestic Production Activities benefit, the impacts of GILTI, and the increase in disallowed deductions for officers compensation, all of which are a result of The Tax Reform Act.

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

Revenues

(in millions)	Year ended December 31, 2017	2016	$ Change	% Change
Product sales:				
BioThrax	$ 286.6	$ 237.0	$ 49.6	21%
Other	134.9	59.3	75.6	127%
Total product sales	421.5	296.3	125.2	42%
Contract manufacturing	68.9	49.1	19.8	40%
Contracts and grants	70.5	143.4	(72.9)	(51%)
Total revenues	$ 560.9	$ 488.8	$ 72.1	15%

The increase in BioThrax sales was substantially due to changes in volume and those changes in volume are driven by the timing of deliveries to the SNS and acceptance of product by the USG. Substantially all of the BioThrax product sales revenues during the year ended December 31, 2017 and 2016 consisted of sales to the USG. The price per unit of BioThrax sold was consistent year over year and as such the change in revenue is due to a variance in the number of units sold.

The increase in other product sales relates primarily to:

- the timing of BAT deliveries of $28.4 million to the SNS;
- international sales for VIGIV and Trobigard of $25.3 million; and
- sales of ACAM2000® and raxibacumab, both acquired in October 2017, of $20.5 million.

Contract manufacturing:

The increase in Contract manufacturing is primarily due to:

- manufacturing services provided to third parties; and
- manufacturing services performed for third party development stage product candidates.

Contracts and grants:

The decrease in Contracts and grants revenues primarily reflects a reduction in revenue associated with the successful completion of multiple U.S. Government contracts, as well as reduced R&D activities related to certain ongoing funded development programs, including:

- decreased development funding of $37.7 million related to our CIADM program. This decrease includes a reduction of $20.5 million related to the timing of facility construction activities and $17.1 million related to CIADM task orders (primarily the successful completion of manufacturing development for Ebola monoclonal antibodies);
- decreased development funding of $34.1 million for VIGIV related to the timing of plasma collection; and
- decreased development funding of $6.8 million for large scale manufacturing of BioThrax, primarily due to the successful completion of the Building 55 development program in 2016 that did not recur in 2017.

These decreases were partially offset by an increase in development funding for NuThrax of $6.7 million, primarily related to non-clinical animal studies and manufacturing activities.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $64.4 million, or 49%, to $195.7 million for 2017 from $131.3 million for 2016. The increase was primarily attributable to:

- the increase in RSDL deliveries to the DoD along with the timing of non-cash fair value adjustments to the contingent consideration liability;
- timing of BAT sales to the SNS;
- timing of international sales for VIGIV and Trobigard;
- sales of the newly acquired ACAM2000 and raxibacumab products (both acquired October 2017); and
- increased costs associated with the expansion of our contract manufacturing business.

These increases were partially offset by the increase in the 2016 BioThrax cost per dose sold associated with lower production yield in the period in which the doses sold were produced.

We have reclassified amortization of intangible assets for the years ended December 31, 2017 and 2016 from cost of product sales and contract manufacturing to amortization of intangible assets to conform to the current period presentation on our consolidated statements of operations.

Research and Development Expenses

Research and development expenses decreased by $10.9 million, or 10%, to $97.4 million for 2017 from $108.3 million for 2016.

The decrease in research and development expense was primarily attributable to reduced development activities attributable to:

- manufacturing development of Ebola monoclonal antibodies related to our CIADM task orders; and
- plasma collection related to our VIGIV program.

These decreases were partially offset by increased research and development activity primarily attributable to:

- formulation development activities, along with screening of molecules within the series, related to our EV-035 series of molecules; and
- preparation for a clinical trial related to our ZIKV-IG program (which was completed in 2018).

Net of contracts and grants revenues, we incurred net research and development expenses of $27.0 million during 2017. Net of contracts and grants revenues, our research and development expenses were fully funded during 2016, resulting in a net contribution from funded development programs of $35.1 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $0.2 million to $143.5 million for 2017 from $143.7 million for 2016. The decrease was primarily attributable to a decrease in costs associated with the restructuring activities at our Lansing, Michigan site during 2016, partially offset by an increase in professional services to support our strategic growth initiatives, along with an increase in compensation related costs.

Total Other Income (Expense), Net

Total other income (expense), net decreased by $0.6 million, or 10%, to $5.7 million for 2017 from $6.3 million for 2016. The decrease was primarily attributable to a decrease in interest expense due in part to the conversion of the vast majority of the outstanding convertible debt to equity in the fourth quarter.

Income Taxes

Provision for income taxes decreased by $0.7 million, or 2%, to $36.0 million for 2017 from $36.7 million for 2016. The provision for income taxes for 2017 resulted primarily from our income before provision for income taxes of $118.6 million and an effective annual tax rate of approximately 30%. Due to the impact of the Tax Reform Act enacted on December 22, 2017, we recognized a $13.4 million tax benefit as a result of revaluing the U.S. ending net deferred tax liabilities from 35% to the newly enacted U.S. corporate income tax rate of 21%. The tax benefit was fully offset by tax expense of $13.6 million for the transition tax on the deemed mandatory repatriation of undistributed earnings. The provision for income taxes for 2016 resulted primarily from our income before provision for income taxes of $99.2 million and an effective annual tax rate of approximately 37%.

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operating and capital expenditures through cash on hand, cash from operations, debt financing and development funding. We also obtain financing from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the last five years ended December 31, 2018. As of December 31, 2018, we had cash and cash equivalents of $112.2 million. As of December 31, 2018, we believe that we have sufficient liquidity to fund our operations over the next 12 months.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2018, 2017 and 2016.

	Year ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Net cash provided by (used in):			
Operating activities(1)	$ 41.6	$ 208.1	$ 54.7
Investing activities	(897.2)	(249.9)	(76.2)
Financing activities	788.7	(51.4)	(19.8)
Net decrease in cash and cash equivalents	$ (66.9)	$ (93.2)	$ (41.3)

(1) Includes the effect of exchange rate changes on cash and cash equivalents.

Operating Activities:

Net cash provided by operating activities including the impact of foreign currency of $41.6 million in 2018 was primarily due to our net income excluding non-cash items of $160.9 million, offset by $119.1 million of negative changes in working capital. Cash outflow includes an increase in accounts receivable related to the timing of collection of amounts billed under our contract with the USG for BioThrax in the fourth quarter of 2018, a decrease in accrued expenses and other liabilities, accounts payable and prepaid expenses and other assets.

Net cash provided by operating activities including the impact of foreign currency of $208.1 million in 2017 was primarily due to our net income excluding non-cash items of $154.4 million and changes in working capital which resulted in a net cash inflow of $53.7 million. Cash inflows include activity the timing of accounts payable associated with ADM, an increase in deferred revenue and an increase in income taxes payable (primarily due to the transition tax on the deemed mandatory repatriation of undistributed earnings).

Net cash provided by operating activities including the impact of foreign currency of $54.7 million in 2016 was primarily due to our net income excluding non-cash items of $98.9 million and changes in working capital which resulted in a net cash outflow of $44.3 million. Cash outflow includes the timing of collection of accounts receivables related to amounts billed (primarily to the CDC), unpaid balances in accounts payable associated with ADM and increase in inventories related to BioThrax.

Investing Activities:

Net cash used in investing activities of $897.2 million in 2018 was primarily due to our acquisitions of Adapt and PaxVax, along with software, infrastructure and equipment investments.

Net cash used in investing activities of $249.9 million in 2017 was primarily due to our acquisitions of ACAM2000 and Raxibacumab, along with software, infrastructure and equipment investments.

Net cash used in investing activities of $76.2 million in 2016 was primarily due to expansion at our Bayview CIADM site, along with software, infrastructure and equipment investments.

Financing Activities:

Net cash provided by financing activities of $788.7 million in 2018 was primarily due to $798.0 million of proceeds from long-term debt borrowings used to finance a portion of the Adapt and PaxVax acquisitions and for general corporate purposes and $15.9 million in proceeds from the issuance of common stock pursuant to our employee equity awards plan, partially offset by $6.6 million associated with the taxes paid on behalf of employees for equity activity.

Net cash used by financing activities of $51.4 million in 2017 was primarily due to $33.1 million utilized to purchase treasury stock, the payment of a $20.0 million note payable to Aptevo in conjunction with the spin-off, $4.3 million associated with the taxes paid on behalf of employees for equity activity and $10.9 million in contingent obligation payments, partially offset by $19.3 million in proceeds from the issuance of common stock pursuant to our employee equity awards plan.

Net cash used by financing activities of $19.8 million in 2016 was primarily due to $45.0 million in cash provided to Aptevo on date of distribution, August 1, 2016 that is partially offset by $17.1 million in proceeds from the issuance of common stock pursuant to employee equity plans and $10.6 million in excess tax benefits from exercise of stock options.

Long-term debt

2017 Credit Agreement

On September 29, 2017, we entered into a senior secured credit agreement (the "2017 Credit Agreement") with four lending financial institutions. The 2017 Credit Agreement provided for a senior secured credit facility of up to $200 million through September 29, 2022.

Amended and Restated Credit Agreement

On October 15, 2018, we entered into an Amended and Restated Credit Agreement (the "Amended Credit Agreement"), which modified the 2017 Credit Agreement. The Amended Credit Agreement (i) increased the revolving credit facility (the "Revolving Credit Facility") from $200 million to $600 million, (ii) extended the maturity of the Revolving Credit Facility from September 29, 2022 to October 13, 2023, (iii) provided for a term loan in the original principal amount of $450 million (the "Term Loan Facility," and together with the Revolving Credit Facility, the "Senior Secured Credit Facilities"), (iv) added several additional lenders, (v) amended the applicable margin such that borrowings with respect to the Revolving Credit Facility will bear interest at the annual rate described below, (vi) amended the provision relating to incremental credit facilities such that we may request one or more incremental term loan facilities, or one or more increases in the commitments under the Revolving Credit Facility (each an "Incremental Loan"), in any amount if, on a pro forma basis, our consolidated secured net leverage ratio does not exceed 2.50 to 1.00 after such incurrence, plus $200 million and (vii) amended the maximum consolidated net leverage ratio financial covenant from 3.50 to 1.0 (subject to 0.50% step up in connection with material acquisitions) to the maximum consolidated net leverage ratio described below.

In October 2018, we borrowed $318 million under the Revolving Credit Facility and $450 million under the Term Loan Facility to finance a portion of the consideration for the PaxVax and Adapt acquisitions and related expenses.

For the years ended December 31, 2018 and 2017, we capitalized $13.4 million and $1.4 million, respectively, of debt issuance costs.

Borrowings under the Revolving Credit Facility and the Term Loan Facility will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.00% per annum, depending on our consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a eurocurrency rate for an interest period of one month plus 1%) plus a margin ranging from 0.25% to 1.00%, depending on our consolidated net leverage ratio. We are required to make quarterly payments under the Amended Credit Agreement for accrued and unpaid interest on the outstanding principal balance, based on the above interest rates. In addition, we are required to pay commitment fees ranging from 0.15% to 0.30% per annum, depending on our consolidated net leverage ratio, in respect of the average daily unused commitments under the Revolving Credit Facility. We are to repay the outstanding principal amount of the Term Loan Facility in quarterly installments based on an annual percentage equal to 2.5% of the original principal amount of the Term Loan Facility during each of the first two years of the Term Loan Facility, 5% of the original principal amount of the Term Loan Facility during the third year of the Term Loan Facility and 7.5% of the original principal amount of the Term Loan Facility during each year of the remainder of the term of the Term Loan Facility until the maturity date of the Term Loan Facility, at which time the entire unpaid principal balance of the Term Loan Facility will be due and payable. We have the right to prepay the Term Loan Facility without premium or penalty. The Revolving Credit Facility and the Term Loan Facility mature (unless earlier terminated) on October 13, 2023.

The Amended Credit Agreement also requires mandatory prepayments of the Term Loan Facility in the event that we or our Subsidiaries (a) incur indebtedness not otherwise permitted under the Amended Credit Agreement or (b) receive cash proceeds in excess of $100 million during the term of the Amended Credit Agreement from certain dispositions of property or from casualty events involving their property, subject to certain reinvestment rights.

The Amended Credit Agreement contains affirmative and negative covenants customary for financings of this type. Negative covenants in the Amended Credit Agreement, among other things, limit our ability to: incur indebtedness and liens; dispose of assets; make investments including loans, advances, guarantees, or acquisitions (other than permitted acquisitions, subject to compliance with the financial covenants and certain other conditions); and enter into certain merger or consolidation transactions. The Amended Credit Agreement also contains financial covenants, including (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, and (2) a maximum consolidated net leverage ratio of 4.00 to 1.00 through September 29, 2019, 3.75 to 1.00 from September 30, 2019 through September 29, 2020 and 3.50 to 1.00 thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition, subject to the terms and conditions of the Amended Credit Agreement. Each of the ratios referred to in the foregoing clauses (1) and (2) is calculated on a consolidated basis for each consecutive four fiscal quarter period.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures, debt service requirements and any future repurchase of our common stock from the following sources:

- existing cash and cash equivalents;
- net proceeds from the sale of our products and contract manufacturing services;
- development contracts and grants funding; and
- our Senior Secured Credit Facilities and any other lines of credit we may establish from time to time.

There are numerous risks and uncertainties associated with product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including (but not limited to):

- the level, timing and cost of product sales and contract manufacturing services;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the extent to which we repurchase additional common stock under our authorized share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements.

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our Senior Secured Credit Facilities, which could limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities, buying back shares or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

We are not restricted under the terms of the indenture governing our 2.875% Convertible Senior Notes due 2021 from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our

notes that could have the effect of diminishing our ability to make payments on our indebtedness. However, our Senior Secured Credit Facilities restricts our ability to incur additional indebtedness, including secured indebtedness.

Economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, operating results, financial condition and cash flows would be adversely affected, and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2018:

	Payments due by period				
(in millions)	**Total**	**Less than 1 year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 years**
Contractual obligations:					
Long-term indebtedness	$ 836.6	$ 14.3	$ 103.3	$ 719.0	$ -
Operating lease obligations	15.5	3.4	5.0	4.6	2.5
Deemed mandatory repatriation tax (1)	11.3	1.1	4.2	6.0	-
Purchase commitments	66.7	60.1	6.6	-	-
Total contractual obligations	$ 930.1	$ 78.9	$ 119.1	$ 729.6	$ 2.5

(1) U.S. federal income tax on deemed mandatory repatriation is payable over 8 years pursuant to the Tax Reform Act.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with GAAP, which requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements included in Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K and accompanying notes. Management considers an accounting policy to be critical if it is important to reporting our financial condition and results of operations, and if it requires significant judgment and estimates on the part of management in its application. We consider policies relating to the following matters to be critical accounting policies:

§ Revenue recognition;
§ Mergers and acquisitions;
§ Contingent consideration; and
§ Income taxes.

We base our estimates on historical experience and on various other assumptions 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 and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of additional risks arising from our operations, see “Item 1A—Business—Risk Factors” in this 2018 Annual Report.

Market Risks

Our exposure to market risk is currently confined to our cash and cash equivalents. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we believe that an increase in market rates would likely not have a significant impact on the realized value of our investments, but any increase in market rates would likely increase the interest expense associated with our debt.

Interest Rate Risk

We have debt with a mix of fixed and variable rates of interest. Floating rate debt carries interest based generally on the eurocurrency, as defined in our Amended Credit Agreement, plus an applicable margin. Increases in interest rates could therefore increase the associated interest payments that we are required to make on this debt. See Note 11, "Long-term debt," to the Notes of our consolidated financial statements included in this 2018 Annual Report under the caption Item 8, "Financial Statements and Supplementary Data.”

We have assessed our exposure to changes in interest rates by analyzing the sensitivity to our operating results assuming various changes in market interest rates. A hypothetical increase of one percentage point in the eurocurrency rate as of December 31, 2018 would increase our interest expense by approximately $8.0 million annually.

Foreign Currency Exchange Rate Risk

We have exposure to foreign currency exchange rate fluctuations worldwide and primarily with respect to the Euro, Canadian dollar, Swiss franc and British pound. We manage our foreign currency exchange rate risk primarily by incurring, to the extent practicable, operating and financing expenses in the local currency in the countries in which we operate.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Emergent BioSolutions Inc. and subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and subsidiaries (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income**,** changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15 (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 21, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note 2 to the consolidated financial statements, the Company changed its method for accounting for revenue in 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, and the amendments in ASUs 2015-14, 2016-08, 2016-10, 2016-12, 2016-20 and 2017-14.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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 financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2004.
Baltimore, Maryland
February 21, 2019

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Balance Sheets
(in millions, except per share data)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 112.2	$ 178.3
Restricted cash	0.2	1.0
Accounts receivable, net	262.5	143.7
Inventories	205.8	142.8
Income tax receivable, net	8.6	2.4
Prepaid expenses and other current assets	31.5	17.2
Total current assets	620.8	485.4
Property, plant and equipment, net	510.2	407.2
Intangible assets, net	761.6	119.6
In-process research and development	50.0	-
Goodwill	259.7	49.1
Deferred tax assets, net	13.4	2.8
Other assets	13.7	6.1
Total assets	$ 2,229.4	$ 1,070.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 80.7	$ 41.8
Accrued expenses and other current liabilities	30.7	4.8
Accrued compensation	58.2	37.9
Long-term indebtedness, current portion	10.1	-
Contingent consideration, current portion	5.6	2.4
Income taxes payable, net	4.5	-
Deferred revenue, current portion	10.6	13.2
Total current liabilities	200.4	100.1
Contingent consideration, net of current portion	54.4	9.9
Long-term indebtedness, net of current portion	784.5	13.5
Deferred tax liability	67.5	-
Income taxes payable	11.2	12.5
Deferred revenue, net of current portion	62.5	17.3
Other liabilities	38.0	4.6
Total liabilities	1,218.5	157.9
Stockholders' equity:		
Preferred stock, $0.001 par value; 15.0 shares authorized, 0 shares issued and outstanding at both December 31, 2018 and 2017	-	-
Common stock, $0.001 par value; 200.0 shares authorized, 52.4 shares issued and 51.2 shares outstanding at December 31, 2018; 50.6 shares issued and 49.4 shares outstanding at December 31, 2017	0.1	0.1
Treasury stock, at cost, 1.2 common shares at both December 31, 2018 and 2017	(39.6)	(39.5)
Additional paid-in capital	688.6	618.3
Accumulated other comprehensive loss	(5.5)	(3.7)
Retained earnings	367.3	337.1
Total stockholders' equity	1,010.9	912.3
Total liabilities and stockholders' equity	$ 2,229.4	$ 1,070.2

The accompanying notes are an integral part of the consolidated financial statements.

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Operations
(in millions, except per share data)

	Year Ended December 31,		
	2018	**2017**	**2016**
Revenues:			
Product sales	$ 606.5	$ 421.5	$ 296.3
Contract manufacturing	98.9	68.9	49.1
Contracts and grants	77.0	70.5	143.4
Total revenues	782.4	560.9	488.8
Operating expenses:			
Cost of product sales and contract manufacturing	322.3	187.7	126.3
Research and development	142.8	97.4	106.9
Selling, general and administrative	202.5	142.9	143.1
Amortization of intangible assets	25.0	8.6	7.0
Total operating expenses	692.6	436.6	383.3
Income from operations	89.8	124.3	105.5
Other income (expense):			
Interest expense	(9.9)	(6.6)	(7.6)
Other income (expense), net	1.6	0.9	1.3
Total other income (expense), net	(8.3)	(5.7)	(6.3)
Income from continuing operations before provision for income taxes	81.5	118.6	99.2
Provision for income taxes	18.8	36.0	36.7
Net income from continuing operations	62.7	82.6	62.5
Net loss from discontinued operations	-	-	(10.7)
Net income	$ 62.7	$ 82.6	$ 51.8
Net income per share from continuing operations-basic	$ 1.25	$ 1.98	$ 1.56
Net loss per share from discontinued operations-basic	-	-	(0.27)
Net income per share-basic	$ 1.25	$ 1.98	$ 1.29
Net income per share from continuing operations-diluted	$ 1.22	$ 1.71	$ 1.35
Net loss per share from discontinued operations-diluted	-	-	(0.22)
Net income per share-diluted (1)	$ 1.22	$ 1.71	$ 1.13
Weighted-average number of shares - basic	50.1	41.8	40.2
Weighted-average number of shares - diluted	51.4	50.3	49.3

(1) See "Earnings per share" footnote for details on calculation.

The accompanying notes are an integral part of the consolidated financial statements.

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Comprehensive Income
(in millions)

	December 31,		
	2018	**2017**	**2016**
Net income	$ 62.7	$ 82.6	$ 51.8
Other comprehensive income (loss), net of tax:			
Currency translation adjustments	(1.6)	0.6	(1.6)
Unrealized losses on pension benefit obligation	(0.2)	-	-
Other comprehensive income (loss), net of tax	(1.8)	0.6	(1.6)
Comprehensive income	$ 60.9	$ 83.2	$ 50.2

The accompanying notes are an integral part of the consolidated financial statements.

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(in millions)

	Year Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net income	$ 62.7	$ 82.6	$ 51.8
Adjustments to reconcile to net cash provided by (used in) operating activities:			
Stock-based compensation	23.2	15.2	18.5
Depreciation and amortization	62.2	42.6	38.2
Deferred income taxes	8.6	3.3	5.2
Change in fair value of contingent obligations	3.1	7.8	(10.8)
Impairment and abandonment of long-lived assets	-	1.9	5.6
Excess tax benefits from stock-based compensation	-	-	(10.6)
Other	1.1	1.0	1.0
Changes in operating assets and liabilities, net of business acquisitions:			
Accounts receivable	(94.2)	(4.8)	(22.4)
Inventories	(1.9)	6.1	(9.0)
Income taxes	(5.1)	20.1	(3.4)
Prepaid expenses and other assets	(7.9)	(3.7)	(2.1)
Accounts payable	(7.0)	16.1	(14.8)
Accrued expenses and other liabilities	(11.6)	1.6	0.6
Accrued compensation	8.4	3.3	2.2
Deferred revenue	0.2	15.0	4.6
Net cash provided by operating activities	41.8	208.1	54.6
Cash flows from investing activities:			
Purchases of property, plant and equipment	(72.1)	(54.8)	(76.2)
Proceeds from sale of assets	2.6	-	-
Asset acquisitions	-	(77.6)	-
Business acquisitions, net of cash acquired	(827.7)	(117.5)	-
Net cash used in investing activities	(897.2)	(249.9)	(76.2)
Cash flows from financing activities:			
Proceeds from long-term debt obligations	798.0	-	-
Proceeds from issuance of common stock upon exercise of stock options	15.9	19.3	17.1
Excess tax benefits from stock-based compensation	-	-	10.6
Debt issuance costs	(13.4)	(1.4)	-
Taxes paid on behalf of employees for equity activity	(6.6)	(4.3)	(1.1)
Principal payments on long-term indebtedness	(2.8)	-	-
Payment of notes payable to Aptevo	-	(20.0)	-
Distribution to Aptevo	-	-	(45.0)
Contingent consideration payments	(3.4)	(10.9)	(1.4)
Receipts and payments of restricted cash	1.1	(1.0)	-
Purchase of treasury stock	(0.1)	(33.1)	-
Net cash (used in) provided by financing activities	788.7	(51.4)	(19.8)
Effect of exchange rate changes on cash and cash equivalents	(0.2)	-	0.1
Net decrease in cash and cash equivalents	(66.9)	(93.2)	(41.3)
Cash and cash equivalents at beginning of year (1)	179.3	272.5	312.8
Cash and cash equivalents at end of year (1)	$ 112.4	$ 179.3	$ 271.5
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 10.2	$ 8.4	$ 8.2
Cash paid during the year for income taxes	$ 14.0	$ 12.0	$ 10.1
Supplemental information on non-cash investing and financing activities:			
Issuance of common stock to acquire Adapt Pharma	$ 37.7	$ -	$ -
Purchases of property, plant and equipment unpaid at year end	$ 14.7	$ 4.6	$ 13.5

(1) As of December 31, 2018 and December 31, 2017, the balance includes restricted cash of $0.2 million and $1.0 million, respectively.

The accompanying notes are an integral part of the consolidated financial statements.

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statement of Changes in Stockholders' Equity
(in millions, except per share data)

	$0.001 Par Value Common Stock		Additional Paid-In	Treasury Stock		Accumulated Other Comprehensive	Retained	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Loss	Earnings	Equity
Balance at December 31, 2015	39.8	$ -	$ 318.0	(0.4)	$ (6.4)	$ (2.7)	$ 351.1	$ 660.0
Employee equity plans activity	1.2	-	34.4	-	-	-	-	34.4
Separation of Aptevo	-	-	-	-	-	-	(148.4)	(148.4)
Net income	-	-	-	-	-	-	51.8	51.8
Other comprehensive loss	-	-	-	-	-	(1.6)	-	(1.6)
Balance at December 31, 2016	41.0	$ -	$ 352.4	(0.4)	$ (6.4)	$ (4.3)	$ 254.5	$ 596.2
Employee equity plans activity	1.1	-	28.0	-	-	-	-	28.0
Shares issued to extinguish convertible notes	8.5	0.1	237.9	-	-	-	-	238.0
Treasury stock	-	-	-	(0.8)	(33.1)	-	-	(33.1)
Net income	-	-	-	-	-	-	82.6	82.6
Other comprehensive income	-	-	-	-	-	0.6	-	0.6
Balance at December 31, 2017	50.6	$ 0.1	$ 618.3	(1.2)	$ (39.5)	$ (3.7)	$ 337.1	$ 912.3
Adoption of new accounting standard (ASC 606), net of tax	-	-	-	-	-	-	(32.5)	(32.5)
Balance at January 1, 2018	50.6	0.1	618.3	(1.2)	(39.5)	(3.7)	304.6	879.8
Employee equity plans activity	1.1	-	32.6	-	-	-	-	32.6
Issuance of common stock in acquisition	0.7	-	37.7	-	-	-	-	37.7
Treasury stock	-	-	-	-	(0.1)	-	-	(0.1)
Net income	-	-	-	-	-	-	62.7	62.7
Other comprehensive loss	-	-	-	-	-	(1.8)	-	(1.8)
Balance at December 31, 2018	52.4	$ 0.1	$ 688.6	(1.2)	$ (39.6)	$ (5.5)	$ 367.3	$ 1,010.9

The accompanying notes are an integral part of the consolidated financial statements.

1. Nature of the business and organization

Organization and business

Emergent BioSolutions Inc. (the "Company" or "Emergent") is a global life sciences company focused on providing specialty products for civilian and military populations that address accidental, intentional and naturally occurring public health threats ("PHTs," each a "PHT").

The Company is focused on innovative preparedness and response products and solutions addressing the following four distinct PHT categories: Chemical, Biological, Radiological, Nuclear and Explosives ("CBRNE"); emerging infectious diseases ("EID"); travelers' diseases; and opioids. The Company has a product portfolio of eleven products (vaccines, antibody therapeutics, and drug-device combination products) that generate a majority of our revenue. The U.S. government (the "USG') is the Company's largest customer and provides us with substantial funding for the development of a number of its product candidates.

The Company's product portfolio includes:

Vaccines and Anti-Infectives

- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration ("FDA"), for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera; and
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever.

Devices

- NARCAN® (naloxone HCl) Nasal Spray, the first and only needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard™ (atropine sulfate, obidoxime chloride), an auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride, as a nerve agent countermeasure. This product is not currently approved or cleared by the FDA or any similar regulatory body and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Antibody Therapeutics

- raxibacumab (Anthrax Monoclonal), the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;
- Anthrasil® [Anthrax Immune Globulin Intravenous (Human)], the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax;
- BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], the only heptavalent antibody therapeutic licensed by the FDA and Health Canada for the treatment of botulism; and
- VIGIV [Vaccinia Immune Globulin Intravenous (Human)], the only antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination.

2. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying consolidated financial statements include the accounts of Emergent and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Reclassification

The Company has reclassified amortization of intangible assets for the years ended December 31, 2017 and 2016 from cost of product sales and contract manufacturing to amortization of intangible assets to conform to the current period presentation on the Company's consolidated statements of operations.

Use of estimates

The preparation of financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates, judgments and assumptions that affect the amounts and disclosures reported in the consolidated financial statements and accompanying notes. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluations could change. These estimates are sometimes complex, sensitive to changes in assumptions and require fair value determinations using Level 3 fair value measurements. Actual results may differ materially from those estimates.

Estimates and judgments inherent in the preparation of the consolidated financial statements include accounting for asset impairments, revenue recognition, allowances for doubtful accounts, inventory, depreciation and amortization, business combinations, stock-based compensation, income taxes, and other contingencies.

Cash, cash equivalents and restricted cash

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions. Also, the Company maintains cash balances with financial institutions in excess of insured limits. The Company does not anticipate any losses with such cash balances. Restricted cash includes cash that is not readily available for use in the Company's operating activities. Restricted cash is primarily comprised of cash pledged under letters of credit.

Fair value measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to

measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value include:

Level 1 — Observable inputs for identical assets or liabilities such as quoted prices in active markets;
Level 2 — Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
Level 3 — Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The Company measures and records contingent purchase consideration using level 3 fair value measurements in the accompanying financial statements. The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The carrying amounts of the Company's long-term debt arrangements approximates their fair values due to variable interest rates which fluctuate with changes in market rates.

Significant customers and accounts receivable

Billed accounts receivable are stated at invoice amounts and consist primarily of amounts due from the USG, as well as amounts due under reimbursement contracts with other government entities and non-government organizations. If necessary, the Company records a provision for doubtful receivables to allow for amounts which may be unrecoverable. This provision is based upon an analysis of the Company's prior collection experience, customer creditworthiness and current economic trends. Unbilled accounts receivable relates to various service contracts for which work has been performed, though invoicing has not yet occurred.

Concentrations Risk

Customers

The Company has long-term contracts with the USG that expire at various times from 2019 through 2027. The Company has derived a significant portion of its revenue from sales of BioThrax under contracts with the USG. The Company's current Centers for Disease Control ("CDC") contract does not necessarily increase the likelihood that it will secure future comparable contracts with the USG. The Company expects that a significant portion of the business will continue to be under government contracts that present a number of risks that are not typically present in the commercial contracting process. USG contracts for BioThrax are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of BioThrax to customers in addition to the USG, which would harm its growth opportunities. The Company may not be able to manufacture BioThrax consistently in accordance with FDA specifications.

Although the Company seeks expand its customer base and to renew its agreements with its customers prior to expiration of a contract, a delay in securing a renewal or a failure to secure a renewal or a renewal on less favorable terms may have a material adverse effect on the Company’s financial condition and results of operations.

The Company’s trade receivables do not represent a significant concentration of credit risk. The USG accounted for more than 76%, 78% and 86% of total consolidated revenues for 2018, 2017 and 2016, respectively, and more than 76% and 89% of total accounts receivable as of December 31, 2018 and 2017, respectively. Because accounts receivable consists primarily of amounts due from the USG for product sales and from government agencies under government grants and development contracts, management does not deem the credit risk to be significant.

Financial Institutions

Cash and cash equivalents are maintained with several financial institutions. The Company has deposits held with banks that exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and are maintained with financial institutions of reputable credit and, therefore, bear minimal credit risk.

Lender Counterparties

There is a risk that the counterparties associated with the Company’s revolving credit facility will not be available to fund as obligated under the terms of the facility and that the Company may, at the time of such unavailability to fund. If funding under the revolving credit facility is unavailable, the Company may have to acquire a replacement credit facility from different counterparties at a higher cost or may be unable to find a suitable replacement. Typically, the Company seeks to manage such risks from its revolving credit facility by contracting with experienced large financial institutions and monitoring the credit quality of its lenders. As of December 31, 2018, the Company did not anticipate nonperformance by any of its counterparties.

Inventories

Inventories are stated at the lower of cost or net realizable value with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses (including fixed production-overhead costs) and includes the services and products of third-party suppliers. The Company analyzes its inventory levels quarterly and writes down, in the applicable period, inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. The Company also writes off, in the applicable period, the costs related to expired inventory. Costs of purchased inventories are recorded using weighted-average costing. The Company determines normal capacity for each production facility and allocates fixed production-overhead costs on that basis.

The Company records inventory acquired in business acquisitions utilizing the comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs.

Property, plant and equipment

Property, plant and equipment are stated at cost less accumulated depreciation and impairments. Depreciation is computed using the straight-line method over the following estimated useful lives:

Buildings	31-39 years
Building improvements	10-39 years
Furniture and equipment	3-15 years
Software	3-7 years or product life
Leasehold improvements	Lesser of the asset life or lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

The Company capitalizes internal-use software when both (a) the software is internally developed, acquired, or modified solely to meet the entity’s internal needs and (b) during the software’s development or modification, no substantive plan either exists or is being developed to market the software externally. Capitalization of qualifying internal-use software costs begins when the preliminary project stage is completed, management with the relevant authority, implicitly or explicitly, authorizes and commits to the funding of the software project, and it is probable that the project will be completed and the software will be used to perform the function intended.

The Company determines the fair value of the property, plant and equipment acquired in a business combination utilizing either the cost approach or the sales comparison approach. The cost approach is determined by establishing replacement cost of the asset and then subtracting any value that has been lost

due to economic obsolescence, functional obsolescence, or physical deterioration. The sales comparison approach determines an asset is equal to the market price of an asset of comparable features such as design, location, size, construction, materials, use, capacity, specification, operational characteristics and other features or descriptions.

Income taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases and net operating loss and research and development tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

Deferred income tax effects of transactions reported in different periods for financial reporting and income tax return purposes are recognized under the asset and liability method of accounting for income taxes. This method gives consideration to the future tax consequences of the deferred income tax items and immediately recognizes changes in income tax laws in the year of enactment. On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act (the "Tax Reform Act"). Further information on the tax impacts of the Tax Reform Act is included in Note 12 of the Company's consolidated financial statements.

The Company's ability to realize deferred tax assets depends upon future taxable income as well as the limitations discussed below. For financial reporting purposes, a deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized prior to expiration. The Company considers future taxable income and ongoing tax planning strategies in assessing the need for valuation allowances. In general, if the Company determines that it is more likely than not to realize more than the recorded amounts of net deferred tax assets in the future, the Company will reverse all or a portion of the valuation allowance established against its deferred tax assets, resulting in a decrease to the provision for income taxes in the period in which the determination is made. Likewise, if the Company determines that it is not more likely than not to realize all or part of the net deferred tax asset in the future, the Company will establish a valuation allowance against deferred tax assets, with an offsetting increase to the provision for income taxes, in the period in which the determination is made.

Under sections 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined therein, there are annual limitations on the amount of net operating losses and deductions that are available. The Company has recognized the portion of net operating losses and research and development tax credits acquired that will not be limited and are more likely than not to be realized.

Because tax laws are complex and subject to different interpretations, significant judgment is required. As a result, the Company makes certain estimates and assumptions, in (1) calculating the Company's income tax expense, deferred tax assets and deferred tax liabilities, (2) determining any valuation allowance recorded against deferred tax assets and (3) evaluating the amount of unrecognized tax benefits, as well as the interest and penalties related to such uncertain tax positions. The Company's estimates and assumptions may differ significantly from tax benefits ultimately realized.

Acquisitions

In determining whether an acquisition is a business combination versus an asset acquisition, the accounting guidance requires an entity to first evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If that threshold is met, the set of assets and activities is not a business and therefore treated as an asset acquisition. If that threshold is not met, the entity evaluates whether the set meets the definition of a business. If an acquired asset or asset group does not meet the definition of a business, the transaction is accounted for as an asset acquisition. Otherwise, the acquisition is treated as a business combination.

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions and generally use Level 3 fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair values that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the merger or acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an asset acquisition and recorded at cost rather than a business combination and, therefore, no goodwill will be recorded.

The fair values of intangible assets, including acquired in-process research and development ("IPR&D"), are determined utilizing information available at or near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, the Company will make a separate determination as to the remaining useful life of the asset and begin amortization. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to current products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's discounted projected net cash flows. The Company's estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels, the performance of competing products where applicable, relevant industry and therapeutic area growth drivers and factors, current and expected trends in technology and product life cycles, the time and investment that will be required to develop products and technologies, the ability to obtain marketing and regulatory approvals, the ability to manufacture and commercialize the products, the extent and timing of potential new product introductions by the Company's competitors, and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate. Indefinite-lived intangible assets are tested for impairment annually or whenever events or changes in circumstances indicate that its carrying amount may not be recoverable.

Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized.

Asset Impairment Analysis

Goodwill and Indefinite-lived Intangible Assets

Goodwill is allocated to the Company's reporting units, which are one level below its operating segment. The Company evaluates goodwill and other indefinite-lived intangible assets for impairment annually as of October 1 and earlier if an event or other circumstance indicates that we may not recover the carrying value of the asset. If the Company believes that as a result of its qualitative assessment it is more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, the quantitative impairment test is not required. If however it is determined that it is not more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, a quantitative test is required.

The quantitative goodwill impairment test is performed using a two-step process. The first step of the process is to compare the fair value of a reporting unit with its carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill of the reporting unit is

not impaired and the second step of the quantitative impairment test is not necessary. If the carrying amount of a reporting unit exceeds its fair value, the second step of the quantitative goodwill impairment test is required to be performed to measure the amount of impairment loss, if any. The second step of the quantitative goodwill impairment test compares the implied fair value of the reporting unit's goodwill with the carrying amount of that goodwill. The implied fair value of goodwill is determined in the same manner as the amount of goodwill recognized in a business combination. In other words, the estimated fair value of the reporting unit's identifiable net assets excluding goodwill is compared to the fair value of the reporting unit as if the reporting unit had been acquired in a business combination and the fair value of the reporting unit was the purchase price paid. If the carrying amount of the reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess.

Following a qualitative assessment indicating that it is not more likely than not that the fair value of the indefinite lived intangible asset exceeds its carrying amount, impairment of other intangible assets not subject to amortization involves a comparison of the estimated fair value of the intangible asset with its carrying value. If the carrying value of the intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. Determining fair value requires the exercise of judgment about appropriate discount rates, perpetual growth rates and the amount and timing of expected future cash flows.

The Company used a qualitative assessment for our goodwill impairment testing for 2018 and 2017. The qualitative evaluation completed during the years ended December 31, 2018 and 2017 indicated no impairment losses. The Company did not have material indefinite lived intangible assets until its acquisitions which were completed in the fourth quarter of 2018.

Long-lived Assets

Long-lived assets such as intangible assets and property, plant and equipment are not required to be tested for impairment annually. Instead, long-lived assets are tested for impairment whenever circumstances indicate that the carrying amount of the asset may not be recoverable, such as when the disposal of such assets is likely or there is an adverse change in the market involving the business employing the related assets. If an impairment analysis is required, the impairment test employed is based on whether the Company's intent is to hold the asset for continued use or to hold the asset for sale. If the intent is to hold the asset for continued use, the impairment test first requires a comparison of undiscounted future cash flows to the carrying value of the asset. If the carrying value of the asset exceeds the undiscounted cash flows, the asset would not be deemed to be recoverable. Impairment would then be measured as the excess of the asset's carrying value over its fair value. Fair value is typically determined by discounting the future cash flows associated with that asset. If the intent is to hold the asset for sale and certain other criteria are met, the impairment test involves comparing the asset's carrying value to its fair value less costs to sell. To the extent the carrying value is greater than the asset's fair value less costs to sell, an impairment loss is recognized in an amount equal to the difference. Significant judgments used for long-lived asset impairment assessments include identifying the appropriate asset groupings and primary assets within those groupings, determining whether events or circumstances indicate that the carrying amount of the asset may not be recoverable, determining the future cash flows for the assets involved and assumptions applied in determining fair value, which include, reasonable discount rates, growth rates, market risk premiums and other assumptions about the economic environment.

Contingent Consideration

The Company records contingent consideration associated with sales-based royalties, sales-based milestones and development and regulatory milestones at fair value. The fair value model used to calculate this obligation is based on the income approach (a discounted cash flow model) that has been risk adjusted based on the probability of achievement of net sales and achievement of the milestones. The inputs the Company uses for determining the fair value of the contingent consideration associated with sales-based royalties, sales-based milestones and development and regulatory milestones are Level 3 fair value measurements. The Company re-evaluates the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the discount rates and updates in the assumed timing of or achievement of net sales and/or the achievement of development and regulatory milestones. Any future increase in the fair value of the contingent consideration associated with sales-based royalties and sales-based milestones along with development and regulatory milestones are based on an increased likelihood that the underlying net sales or milestones will be achieved.

The associated payment or payments which will become due and payable for sales-based royalties and sales-based milestones associated with products will result in a charge to cost of product sales and contract manufacturing in the period in which the increase is determined. Similarly, any future decrease in the fair value of contingent consideration associated with sales-based royalties and sales-based milestones will result in a reduction in cost of product sales and contract manufacturing. The changes in fair value for potential future sales-based royalties associated with product candidates in development will result in a charge to selling, general and administrative expense in the period in which the increase is determined. Similarly, any future decrease in the fair value of contingent consideration associated with potential future sales-based royalties for products candidates will result in a reduction in selling, general and administrative expense.

The associated payment or payments which will become due and payable for development and regulatory milestones will result in a charge to research and development expense in the period in which the increase is determined. Similarly, any future decrease in the fair value for development and regulatory milestones will result in a reduction in research and development expense.

Revenue recognition

On January 1, 2018 the Company adopted ASC topic 606 using the modified retrospective approach applied to those contracts in effect as of January 1, 2018. Under this transition method, results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported in accordance with historical accounting under Topic 605. See further discussion of the adoption of Topic 606, including the impact to our 2018 financial statements within the recently issued accounting standards section below.

The Company recognizes revenue when the Company's customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services by analyzing the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. To indicate the transfer of control for the Company's product sales and contract manufacturing services, it must have a present right to payment, legal title must have passed to the customer, and the customer must have the significant risks and rewards of ownership. Revenue for long-term development contracts is generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with transferring control of the good or service over time.

Multiple performance obligations

A performance obligation is a promise in a contract to transfer a distinct product or service to a customer and is the unit of account under ASC 606. For contracts with multiple performance obligations, the Company allocates the contract's transaction price to each performance obligation on a relative standalone selling price basis using the Company's best estimate of the standalone selling price of each distinct product or service in the contract. The primary method used to estimate standalone selling price is the price observed in standalone sales to customers, however when prices in standalone sales are not available the Company may use third-party pricing for similar products or services or estimate the standalone selling price. Allocation of the transaction price is determined at the contracts' inception.

Transaction price and variable consideration

Once the performance obligations in the contract have been identified, the Company estimates the transaction price of the contract. The estimate includes amounts that are fixed as well as those that can vary based on expected outcomes of the activities or contractual terms. The Company's variable consideration includes for example consideration transferred under its development contracts with the USG as consideration received can vary based on developmental progression of the product candidate(s). When a contract's transaction price includes variable consideration, the Company evaluates the estimate of the variable consideration to determine whether the estimate needs to be constrained; therefore, the Company includes the variable consideration in the transaction price only to the extent that it is probable that a significant reversal of the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration estimates are updated at each reporting date. There were no constraints or material changes to the Company's variable consideration estimates as of or during the twelve months ended December 31, 2018.

Contract financing

In determining the transaction price, the Company adjusts the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer with a significant benefit of financing the transfer of goods or services to the customer, which is called a significant financing component. The Company does not adjust transaction price for the effects of a significant financing component when the period between the transfer of the promised good or service to the customer and payment for that good or service by the customer is expected to be one year or less.

Product sales

CBRNE

The Company's CBRNE products are as follows: BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT, VIGIV, RSDL and Trobigard. The primary customer for the Company's CBRNE products and the primary source of funding for the development of its CBNRE product candidate portfolio is the USG. The Company's contracts for the sale of CBRNE products generally have a single performance obligation. Certain product sales contracts with the USG include multiple performance obligations, which generally include the marketed product, stability testing associated with that product, expiry extensions and plasma collection. The USG contracts for the sale of the Company's CBRNE products are normally multi-year contracts.

The transaction price for product sales are based on a cost build-up model with a mark-up. For our product sales, we recognize revenue at a "point in time" when the Company’s performance obligations have been satisfied and control of the products transfer to the customer. This “point in time” depends on several factors, including delivery, transfer of legal title, transition of risk and rewards of the product to the customer and the Company's right to payment. The USG contracts for the sale of the Company's CBRNE products also include certain acceptance criteria before title passes to the USG.

Travelers' diseases and Opioids

The Company's travelers' disease and opioid products are as follows: Vivotif, Vaxchora and NARCAN® Nasal Spray. Revenues are recognized when control of the goods are transferred to our customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, chargebacks and rebates under managed care plans are considered in determining the variable consideration. Revenues from sales of products is recognized to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with such variable consideration is subsequently resolved. Product sales revenue is recognized when control has transferred to the customer, which occurs at a point in time, which is typically upon delivery to the customer. Provisions for variable consideration revenues from sales of products are recorded at the net sales price, which includes estimates of variable consideration for which provisions are established and which relate to returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, chargebacks and rebates under managed care plans. Calculating certain of these provisions involves estimates and judgments and the Company determines their expected value based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs’ regulations and guidelines that would impact the amount of the actual rebates, the Company's expectations regarding future utilization rates for these programs and channel inventory data. These provisions reflect the Company's best estimate of the amount of consideration to which the Company is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The Company reassesses the Company's provisions for variable consideration at each reporting date. Historically, adjustments to estimates for these provisions have not been material.

Provisions for returns, specialty distributor fees, wholesaler fees, government rebates and rebates under managed care plans are included within current liabilities in the Company's consolidated balance sheets. Provisions for chargebacks and prompt payment discounts are shown as a reduction in accounts receivable.

Contract manufacturing

The Company performs contract manufacturing services for third parties. Under these contracts, activities can include pharmaceutical product process development, manufacturing and filling services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, laboratory analytical development support, aseptic filling, lyophilization, final packaging and accelerated and ongoing stability studies. These contracts, with a duration that is less than one year, generally include a single performance obligation as the customer benefits from our performance upon full completion of our services. The performance obligation is satisfied when the Company must have a present right to payment because legal title has passed to the customer, the goods are in the customer’s possession with all the risks and rewards of ownership, and the efficacy of the goods has been confirmed. The Company recognizes revenue at a "point in time" based on when the performance obligation to the customer is satisfied.

Contracts and grants

The Company generates contract and grant revenue primarily from cost-plus-fee contracts associated with development of certain product candidates. Revenues from reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. The Company uses this input method to measue progress as the customer has the benefit of access to the development research under these projects and therefore benefits from the Compny’s performance incrementally as research and development activites occur under each project. We consider fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. We analyze costs for contracts and reimbursable grants to ensure reporting of revenues gross versus net is appropriate. Revenue for long-term development contracts is considered variable consideration, because the deliverable is dependent on the successful completion of development and is generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with satifiying the performance obligation over time. The USG contracts for the development of the Company's CBRNE product candidates are normally multi-year contracts. For the three years in the period ended December 31, 2018, 2017, and 2016, the costs incurred under the contracts and grants was 32%, 43% and 67%, respectively, of total research and development expenses incurred.

Research and development

We expense research and development costs as incurred. The Company's research and development expenses consist primarily of:

- personnel-related expenses;
- fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of the Company's clinical trials and obtaining and evaluating data from the Company's clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material; and
- costs of materials used in clinical trials and research and development.

Comprehensive income

Comprehensive income is comprised of net income and other changes in equity that are excluded from net income. The Company includes translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income as well as gains and losses on its pension benefit obligation.

Translation of Foreign Currencies

For our non-U.S. subsidiaries that transact in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign currency exchange rates for the period. Adjustments

resulting from the translation of the financial statements of our foreign operations into U.S. dollars are excluded from the determination of net income and are recorded in accumulated other comprehensive income, a separate component of equity. For subsidiaries where the functional currency of the assets and liabilities differ from the local currency, non-monetary assets and liabilities are translated at the rate of exchange in effect on the date assets were acquired while monetary assets and liabilities are translated at current rates of exchange as of the balance sheet date. Income and expense items are translated at the average foreign currency rates for the period. Translation adjustments of these subsidiaries are included in other income (expense), net in our consolidated statements of income.

Earnings per share

The Company calculates basic earnings per share by dividing net income by the weighted average number of shares of common stock outstanding during the period.

For the year ended December 31, 2018, the Company calculated diluted earnings per share using the treasury method by dividing net income by the weighted average number of shares of common stock outstanding during the period. For the years ended December 31, 2017 and 2016, the Company calculated diluted earnings per share using the if-converted method by dividing the adjusted net income by the adjusted weighted average number of shares of common stock outstanding during the period. The adjusted net income is adjusted for interest expense and amortization of debt issuance cost, both net of tax, associated with the Company's 2.875% Convertible Senior Notes due 2021 (the "Notes"). The weighted average number of diluted shares is adjusted for the potential dilutive effect of the exercise of stock options and the vesting of restricted stock units along with the assumption of the conversion of the Notes, each at the beginning of the period. During the fourth quarter of 2017, the Company issued a notice of termination of conversion rights related to the Notes and issued 8.5 million shares of common stock due to conversions that occurred in 2017.

Accounting for stock-based compensation

The Company has one stock-based employee compensation plan, the Emergent BioSolutions Inc. Stock Incentive Plan (the "Emergent Plan"), which includes both stock options and restricted stock units.

The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plan is determined by the compensation committee of the Company's board of directors, which administers the Emergent Plan. Each equity award granted under the Emergent Plan vests as specified in the relevant agreement with the award recipient and no option can be exercised after ten years from the date of grant. The Company charges the estimated fair value of awards against income on a straight-line basis over the requisite service period, which is generally the vesting period. Where awards are made with non-substantive vesting periods (for instance, where a portion of the award vests upon retirement eligibility), the Company estimate and recognize expense based on the period from the grant date to the date the employee becomes retirement eligible.

The Company determines the fair value of restricted stock units using the closing market price of the Company's common stock on the day prior to the date of grant. The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. Set forth below is a discussion of the Company's methodology for developing each of the assumptions used:

- Expected dividend yield — the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.
- Expected volatility — a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. The Company analyzed its own historical volatility to estimate expected volatility over the same period as the expected average life of the options.
- Risk-free interest rate — the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date on which the option is granted.
- Expected average life of options — the period of time that options granted are expected to remain outstanding, based primarily on the Company's expectation of optionee exercise behavior subsequent to vesting of options.

Pension plans

The Company maintains defined benefit plans for employees in certain countries outside the U.S., including retirement benefit plans required by applicable local law. The plans are valued by independent actuaries using the projected unit credit method. The liabilities correspond to the projected benefit obligations of which the discounted net present value is calculated based on years of employment, expected salary increase, and pension adjustments. The Company reviews its actuarial assumptions on an annual basis and makes modifications to the assumptions based on current rates and trends. Actuarial gains and losses are deferred in accumulated other comprehensive loss, net of tax and are amortized over the remaining service attribution periods of the employees under the corridor method. Differences between the expected long-term return on plan assets and the actual annual return are amortized to net periodic benefit cost over the estimated remaining life as a component of selling, general and adminstrative expenses in the consolidated statements of operations.

Recently issued accounting standards

Recently Adopted

ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09")

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09. ASU No. 2014-09 (known as ASC 606) supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, as well as most industry-specific guidance, and significantly enhances comparability of revenue recognition practices across entities and industries by providing a principles-based, comprehensive framework for addressing revenue recognition issues. The Company adopted ASC 606 as of January 1, 2018 using the modified retrospective method resulting in an adjustment to opening retained earnings of $32.5 million for the cumulative effect of initially applying the new standard.

Under ASC 606, the Company finalized the review of its portfolio of revenue contracts that were not complete as of the adoption date and made its determination of its revenue streams as well as completed extensive contract specific reviews to determine the impact of the new standard on its historical and prospective revenue recognition. Because many of the Company's significant contracts with customers have unique contract terms, the Company reviewed all its non-standard agreements in order to determine the effect of adoption. The Company tested a sample of remaining agreements to verify that there were no changes in accounting based on the assumption that these contracts had similar characteristics and that the effects on the financial statements would not differ materially from applying this guidance to the individual contracts. To estimate the financial impacts of the adoption, the Company did not apply the contract modification practical expedient and retrospectively restated long-term contracts for any contract modifications.

The opening balance sheet adjustment was the result of the Centers for Innovation in Advanced Development and Manufacturing ("CIADM") contract with the Biomedical Advanced Research and Development Authority ("BARDA"). Under ASC 606 at January 1, 2018, the Company determined that the performance obligation under the arrangement is to provide ongoing manufacturing capability to the USG and would recognize the consideration received in the initial 7 year base period on a straight-line basis over a 24-year period as the capability being created during the base period of the contract is being provided to the customer over both the base period contract term as well as 17 additional option periods. As the Company’s performance obligation is providing the USG with continuous access to its production capabilities throughout the contract duration, a time-based measure resulting in straight-line revenue recognition is proportionate to the Company’s progress in satisfying the performance obligation when compared to the total progress. This measure of progress is most reflective of the Company satisfying the performance obligation over time. Beginning in June 2013, the Company was expected to be able to stand ready and be available to respond to the USG and importantly to respond to any task orders that may be issued during the base period and additional option periods. Being able to stand ready to perform in the event of an outbreak is of importance to the USG and by entering into this arrangement with the Company, the USG expected to receive the benefit of having access to Company’s readiness and its capability to immediately respond to public health threats. Prior to June 2013, the Company was performing fulfillment and set-up activities to be able to perform under the contract. The Company concluded the identified stand-ready performance obligations represent a series of distinct services that are substantially the same and have the same pattern of transfer to the customer.

In addition, the Company determined the CIADM contract includes a significant financing component which is included in the transaction price. The Company calculated the financing component using an interest rate the Company had on its other debt obligations at inception of the contract. The difference in revenue recognized under ASC 605 vs. ASC 606, as of the adoption date, was primarily attributable to the difference in the overall consideration or transaction price resulting from different accounting treatment related to options within the contract and the inclusion of a significant financing component under ASC 606.

Prior to the adoption of ASC 606, the Company recognized revenue under the CIADM contract on a straight-line basis, based upon its estimate of the total payments to be received under the contract. The Company analyzes the estimated payments to be received on a quarterly basis to determine if an adjustment to revenue was required. As a result of the adoption of ASC 606, as of January 1, 2018, there was an increase in the deferred revenue liability of $42.4 million and an increase in deferred tax assets of $9.9 million with an offsetting reduction to retained earnings of $32.5 million.

ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory* ("ASU 2016-16")

In October 2016, the FASB issued ASU 2016-16. ASU 2016-16 improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. The new standard will require entities to recognize the income tax consequences of an intra-entity transfer of a non-inventory asset when the transfer occurs. The Company adopted the guidance on January 1, 2018 which did not have a significant impact on the presentation of the Company’s financial statements.

ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15")

In August 2016, the FASB issued Accounting Standard Update ("ASU") 2016-15. ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayments or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The Company adopted the new standard effective January 1, 2018 and has determined the impact of ASU No. 2016-15 on its consolidated financial statements will be related to the settlement of contingent liabilities arising from a business combination.

ASU 2016-18, *Restricted Cash (Topic 230): Statement of Cash Flows* ("ASU 2016-18")

In November 2016, the FASB issued ASU 2016-18. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning of period and end of period balances on the statement of cash flows upon adoption of this standard. The Company adopted the new standard effective January 1, 2018 on a prospective basis.

ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09")

In May 2017, the FASB issued ASU 2017-09. ASU 2017-09 clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company adopted the new standard effective January 1, 2018, which did not have a material impact on its consolidated financial statements.

ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting* ("ASU 2018-07")

In June 2018, the FASB issued ASU 2018-07. ASU 2018-07 expands the scope of Topic 718 to include share-based payments issued to nonemployees for goods and services. ASU No. 2018-07 is intended to reduce cost and complexity and to improve financial reporting for share-based payments issued to nonemployees (for example, service providers, external legal counsel, suppliers, etc.). The standard will be effective after December 15, 2018 for the Company, with early adoption permitted, but no earlier than the Company's adoption date of Topic 606. The Company early adopted the new standard effective April 1, 2018. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

ASU No. 2017-07, *Compensation - Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Costs and Net Periodic Postretirement Benefit Cost* ("ASU 2017-07")

In March 2017, the FASB issued ASU 2017-07. This standard requires that an employer disaggregate the service cost component from the other components of net benefit cost. This standard also provides explicit guidance on how to present the service cost component and the other components of net benefit cost in the statements of income and allows only the service cost component of net benefit cost to be eligible for capitalization. The other components of the net periodic benefit cost must be presented separately from the line items that include service cost and outside of any subtotal of operating income on our consolidated statements of income. The Company adopted this standard on January 1, 2018. The adoption of this standard did not have a material impact on the consolidated financial statements.

ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-07")

In January 2017, the FASB issued ASU 2017-01. This guidance that amends the definition of a business and provides a threshold which must be considered to determine whether a transaction is an acquisition (or disposal) of an asset or a business. Under the current accounting guidance, the minimum inputs and processes required for a “set” of assets and activities to meet the definition of a business is not specified. That lack of clarity has led to broad interpretations of the definition of a business. Under this guidance, when substantially all of the fair value of gross assets acquired is concentrated in a single asset (or group of similar assets), the assets acquired would not represent a business. In addition, in order to be considered a business, an acquisition would have to include at a minimum an input and a substantive process that together significantly contribute to the ability to create an output. The amended guidance also narrows the definition of outputs by more closely aligning it with how outputs are described in FASB guidance for revenue recognition. The guidance is effective on a prospective basis beginning January 1, 2018.

Not Yet Adopted

ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02")

In February 2016, the FASB issued ASU 2016-02. ASU 2016-02 increases transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The standard is effective January 1, 2019, with early adoption permitted. The Company will adopt the new standard effective January 1, 2019 using the modified retrospective approach. An entity that applies the transition provisions at the beginning of the period of adoption records its cumulative adjustment to the opening balance of retained earnings in the period of adoption rather than in the earliest period presented (i.e., January 1, 2019 for a calendar year-end entity that adopts the standard on that date). In this case, an entity continues to apply the legacy guidance in ASC 840, including its disclosure requirements, in the comparative periods presented in the year it adopts the standard.

The Company will take advantage of the transition package of certain practical expedients permitted: ASC 842-10-65-1(f) and ASC 842-10-65-1(g). The Company will make an accounting policy election that will keep leases with an initial term of 12 months or less off of the balance sheet and will result in recognizing those lease payments in the consolidated statements of operations on a straight-line basis over the lease term. In addition, the Company has made an accounting policy election, by class of underlying asset, to not separate non-lease components from lease components and instead to account for each separate lease component, and the non-lease components associated with that lease component, as a single lease component.

While the Company is continuing to assess all potential impacts of the standard, the Company currently expects total liabilities to increase with an offsetting increase to leased assets by an amount not in excess of 5% of total liabilities as of the date of adoption. The difference between these amounts will be recorded as an adjustment to retained earnings. The Company does not believe the standard will materially affect the Company's consolidated net earnings. These estimates, based on the Company's current lease portfolio, may change as it continues to evaluate the new standard. The estimates could also change

due to changes in the lease portfolio, which could include (a) lease volume, (b) lease commencement dates, and (c) renewal option and lease termination expectations. The Company will update its estimates each quarter as changes occur.

ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13")

In June 2016, the FASB issued ASU 2016-13. ASU 2016-13 provides guidance on measurement of credit losses on financial instruments that changes the impairment model for most financial assets and certain other instruments, including trade and other receivables, held-to-maturity debt securities and loans, and that requires entities to use a new, forward-looking "expected loss" model that is expected to generally result in the earlier recognition of allowances for losses. The guidance is effective for annual periods beginning after December 15, 2019, including interim periods within those years, but early adoption is permitted. The Company is evaluating the effect that the pronouncement will have on the Company's consolidated financial statements.

ASU 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* ("ASU 2017-04")

In January 2017, the FASB issued ASU 2017-04. ASU 2017-04 simplifies the subsequent measurement of goodwill and eliminates Step 2 from the goodwill impairment test. ASU 2017-04 is effective for annual and interim goodwill tests beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates on or after January 1, 2017. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

ASU 2018-02, *Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* ("ASU 2018-02")

In February 2018, the FASB issued ASU 2018-02. ASU 2018-02 provides the option to reclassify certain income tax effects related to the Tax Cuts and Jobs Act passed in December of 2017 between accumulated other comprehensive income and retained earnings and also requires additional disclosures. ASU 2018-02 is effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. Adoption of ASU 2018-02 is to be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the tax laws or rates were recognized. The Company is currently evaluating the impact of adopting ASU 2018-02 on its consolidated financial statements.

ASU 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820)* ("ASU 2018-13")

In August 2018, the FASB issued ASU 2018-13. ASU 2018-13 improves the disclosure requirements on fair value measurements. The updated guidance if effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. The Company is currently assessing the timing and impact of adopting the updated provisions.

ASU 2018-14, *Compensation - Retirement Benefits - Defined Benefit Plans - General (Topic 715-20): Disclosure Framework - Changes to the Disclosure Requirements for Defined Benefit Plans* ("ASU 2018-14")

In August 2018, the FASB issued ASU 2018-14. ASU 2018-14 modifies the disclosure requirements for defined benefit pension plans and other postretirement plans. ASU 2018-14 is effective for all entities for fiscal years ending after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-14 on its consolidated financial statements.

ASU 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15")

In August 2018, the FASB issued ASU 2018-15. ASU 2018-15 clarifies the accounting for implementation costs in cloud computing arrangements. ASU 2018-15 is effective for all entities for fiscal years beginning after December 15, 2019, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-15 on its consolidated financial statements.

SEC's Disclosure Update and Simplification

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. Among the amendments is the requirement to present the changes in stockholders' equity in the interim financial statements (either in a separate statement or footnote) in quarterly reports on Form 10-Q. The amendments are effective for all filings made on or after November 5, 2018. However, registrants may begin providing the new interim reconciliations of stockholders' equity in the Form 10-Q for the interim period beginning after the effective date. The Company plans to implement the changes required by these amendments to its Statements of Equity in its Form 10-Q filing for the period ended March 31, 2019.

3. Revenue recognition

The Company operates in one business segment. Therefore, results of the Company's operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. For the year ended December 31, 2018, there was a nominal difference between revenues recognized under ASC 606 and revenues recognized based on the prior revenue recognition guidance for the same period.

For the year ended December 31, 2018, the Company's revenues disaggregated by the major sources was as follows:

(in millions)	**Year Ended December 31, 2018**		
	U.S Government	**Non-U.S. Government**	**Total**
Product sales	$ 526.1	$ 80.4	$ 606.5
Contract manufacturing	—	98.9	98.9
Contracts and grants	71.5	5.5	77.0
Total revenues	$ 597.6	$ 184.8	$ 782.4

Contract liabilities

When performance obligations are not transferred to a customer at the end of a reporting period, the amount allocated to those performance obligations are reflected as deferred revenue on the consolidated balance sheets and are deferred until control of these performance obligations is transferred to the customer. The following table presents the rollforward of deferred revenue contract liabilities:

(in millions)	
Balance at December 31, 2017	$ 30.5
Adoption of new accounting standard (ASC 606)	42.4
Balance at January 1, 2018	72.9
Deferral of revenue	29.3
Recognition of revenue included in beginning of year contract liability	(29.1)
Balance at December 31, 2018	$ 73.1

Transaction price allocated to remaining performance obligations

As of December 31, 2018, the Company had expected future revenues associated with performance obligations that have not been satisfied of approximately $550 million. The Company expects to recognize a majority of these revenues within the next 24 months, with the remainder recognized thereafter. However, the amount and timing of revenue recognition for unsatisfied performance obligations can materially change due to timing of funding appropriations from the USG and the overall success of the Company's development activities associated with its CBRNE product candidates that are then receiving development funding support from the government under development contracts. In addition, the amount of future revenues associated with unsatisfied performance obligations excludes the value associated with unexercised option periods in the Company's contracts (which are not performance obligations as of December 31, 2018).

Contract assets

The Company considers unbilled accounts receivables and deferred costs associated with revenue generating contracts, that are not included in inventory or property, plant and equipments, as contract assets. As of December 31, 2018 and 2017, the Company had contract assets associated with deferred costs of $1.2 million and $2.9 million, respectively, which is included in prepaid expenses and other current assets on the Company's consolidated balance sheets.

Accounts receivable

Accounts receivable including unbilled accounts receivable contract assets consist of the following:

	December 31,	
(in millions)	**2018**	**2017**
Billed, net	$ 234.0	$ 118.9
Unbilled	28.5	24.8
Total, net	$ 262.5	$ 143.7

As of December 31, 2018 and 2017, the Company's accounts receivable balances were comprised of 76% and 89%, respectively, from the USG. The overall decrease in the percentage of accounts receivable attributed to the USG was due primarily to the increase of non-USG related accounts receivable from PaxVax and Adapt, both acquired in October 2018. As of December 31, 2018, allowance for doubtful accounts were de minimis. The Company did not have any allowance for doubtful accounts as of December 31, 2017.

4. Discontinued operations

On August 1, 2016, the Company completed the spin-off of Aptevo through the distribution of 100% of the outstanding shares of common stock of Aptevo to the Company's shareholders (the "Distribution"). After the Distribution, the Company no longer holds shares of Aptevo's common stock. In addition, on August 1, 2016, the Company entered into a non-negotiable, unsecured promissory note with Aptevo to provide an additional $20 million in funding, which the Company paid in January 2017.

The historical statements of operations of Aptevo have been presented as discontinued operations in the consolidated financial statements. Discontinued operations include results of Aptevo's business except for certain allocated corporate overhead costs and certain costs associated with transition services provided by the Company to Aptevo. These allocated costs remain part of continuing operations.

The following table summarizes results from discontinued operations of Aptevo included in the consolidated statements of operations for the year ended December 31, 2016:

(in millions)	**Year ended December 31, 2016**
Revenues:	
Product sales	$ 21.2
Collaborations	0.2
Total revenues	21.4
Operating expense:	
Cost of product sales	11.6
Research and development	18.0
Selling, general and administrative	23.8
Total operating expense	53.4
Loss from discontinued operations before benefit from income taxes	(32.0)
Benefit from income taxes	(21.3)
Net loss from discontinued operations	$ (10.7)

The following table summarizes the cash flows of Aptevo included in the year ended December 31, 2016 consolidated statements of cash flows:

(in millions)	**Year ended December 31, 2016**
Net cash used in operating activities	$ (10.3)
Net cash used in investing activities	(1.9)
Net cash provided by financing activities	7.7
Net decrease in cash and cash equivalents	$ (4.5)

5. Acquisitions

Acquisition of Adapt

On October 15, 2018, the Company completed the acquisition of Adapt Pharma Limited ("Adapt") and its NARCAN® (naloxone HCl) Nasal Spray marketed product, the first and only needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. This acquisition includes the NARCAN® Nasal Spray marketed product and a development pipeline of new treatment and delivery options to address opioid overdose, and approximately 50 employees, located in

the U.S., Canada, and Ireland, including those responsible for supply chain management, research and development, government affairs, and commercial operations. The acquisition will expand the Company's scope of capabilities to deliver critical medical counter measures to its customers.

The preliminary purchase consideration is as follows:

(in millions)	October 15, 2018
Cash	$ 581.5
Equity	37.7
Fair value of contingent purchase consideration	48.0
Total preliminary purchase consideration	$ 667.2

The Company issued 733,309 shares of Common Stock at $60.44 per share, the closing price of Emergent's share price on October 15, 2018, for a total of $44.3 million (inclusive of adjustments). The $44.3 million value of the common stock shares issued has been adjusted to a fair value of $37.7 million considering a discount for lack of marketability due to a two-year lock-up period beginning on October 15, 2018. The remaining consideration payable for the acquisition consists of up to $100 million in cash based on the achievement of certain sales milestones through 2022 which the Company has determined the fair value of to be $48.0 million as of the acquisition date. The fair value of the contingent purchase consideration is based on management's assessment of the potential future realization of the contingent purchase consideration payments. This assessment is based on inputs that have no observable market (Level 3). The obligation is measured using a discounted cash flow model.

This transaction will be accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of Adapt will be recorded as of October 15, 2018, the acquisition date, at their respective fair values, and combined with those of the Company. The purchase price allocation is preliminary as the Company needs to continue to gather data necessary to complete the fair value valuation of various closing balance sheet items such as, but not limited to intangible assets (including acquired in-process research and development ("IPR&D")) acquired and income taxes.

The table below summarizes the preliminary allocation of the purchase price based upon estimated fair values of assets acquired and liabilities assumed at October 15, 2018.

(in millions)	October 15, 2018
Estimated fair value of tangible assets acquired and liabilities assumed:	
Cash	$ 17.7
Accounts receivable	21.3
Inventory	41.4
Prepaid expenses and other assets	7.8
Accounts payable	(32.2)
Accrued expenses and other liabilities	(50.4)
Deferred tax liability, net	(62.4)
Total estimated fair value of tangible assets acquired and liabilities assumed	(56.8)
Acquired in-process research and development	41.0
Acquired intangible asset	534.0
Goodwill	149.0
Total purchase price	$ 667.2

The Company determined the estimated fair value of the intangible asset using the income approach, which is based on the present value of future cash flows. The fair value measurements are based on significant unobservable inputs that are developed by the Company using estimates and assumptions of the respective market and market penetration of the Company's products.

The preliminary estimated fair value of the intangible asset acquired for Adapt's marketed product NARCAN® Nasal Spray is valued at $534.0 million. The Company has determined the useful life of the NARCAN® Nasal Spray intangible asset to be 15 years. The Company estimated the fair value of the NARCAN® Nasal Spray intangible asset using the income approach with a present value discount rate of 10.5%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Adapt. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from the NARCAN® Nasal Spray intangible asset were based on key assumptions including: estimates of revenues and operating profits; and risks related to the viability of and potential alternative treatments in any future target markets.

The intangible asset associated with IPR&D acquired from Adapt is related to a product candidate. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was $41.0 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. The Company estimated the fair value using a present value discount rate of 11%, which is based on the estimated weighted-average cost of capital for companies with that profiles substantially similar to that of Adapt and IPR&D assets at a similar stage of development as the product candidate. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value the IPR&D. The projected cash flows for the product candidate were based on key assumptions including: estimates of revenues and operating profits, considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts (see Note 10).

The Company determined the fair value of the inventory using the comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs.

The Company recorded approximately $149.0 million in goodwill related to the Adapt acquisition, which is calculated as the purchase price paid in excess of the fair value of the tangible and intangible assets acquired representing the future economic benefits the Company expects to receive as a result of the acquisition. The goodwill created from the Adapt acquisition is associated with early stage pipeline products. Substantially all of the goodwill generated from the Adapt acquisition is not expected to be deductible for tax purposes.

The Company has incurred transaction costs related to the Adapt acquisition of approximately $16.3 million for the year ended December 31, 2018, which have been recorded in selling, general and administrative expenses.

Acquisition of PaxVax

On October 4, 2018, the Company completed the acquisition of PaxVax Holding Company Ltd. ("PaxVax"), a company focused on developing, manufacturing, and commercializing specialty vaccines that protect against existing and emerging infectious diseases. This acquisition includes Vivotif®

(Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever, Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera, an adenovirus 4/7 vaccine candidate being developed for military personnel under contract with the DoD, and additional clinical-stage vaccine candidates targeting chikungunya and other emerging infectious diseases, European-based current good manufacturing practices ("cGMP") biologics manufacturing facilities, and approximately 250 employees including those in research and development, manufacturing, and commercial operations with a specialty vaccines salesforce in the U.S. and in select European countries. The products and product candidates within PaxVax's portfolio are consistent with the Company's mission and will expand the Company's core business of addressing PHTs. In addition, the acquisition expands the Company's manufacturing capabilities.

At the closing, the Company paid a cash consideration of $273.1 million (inclusive of closing adjustments). This transaction will be accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of PaxVax will be recorded as of October 4, 2018, the acquisition date, at their respective fair values, and combined with those of the Company. As of the date of this filing, the initial accounting for the PaxVax acquisition is preliminary due to the Company's need to continue to gather data to assess the fair value valuation of property, plant and equipment along with the acquired intangible assets (including IPR&D) and accounting for taxes.

The table below summarizes the preliminary allocation of the purchase consideration based upon estimated fair values of assets acquired and liabilities assumed at October 4, 2018.

(in millions)	**October 4, 2018**
Estimated fair value of tangible assets acquired and liabilities assumed:	
Cash	$ 9.0
Accounts receivable	4.1
Inventory	19.7
Prepaid expenses and other assets	12.2
Property, plant and equipment	57.8
Deferred tax assets, net	3.8
Accounts payable	(3.5)
Accrued expenses and other liabilities	(33.6)
Total estimated fair value of tangible assets acquired and liabilities assumed	69.5
Acquired in-process research and development	9.0
Acquired intangible assets	133.0
Goodwill	61.6
Total purchase consideration	$ 273.1

The preliminary estimated fair value of the intangible assets acquired for PaxVax's marketed products are valued at a total of $133.0 million. The Company has determined that the weighted average useful lives of the intangible assets to be 19 years.

The Company determined the estimated fair value of the intangible assets using the income approach, which is based on the present value of future cash flows. The fair value measurements are based on significant unobservable inputs that are developed by the Company using estimates and assumptions of the respective market and market penetration of the Company's products.

The Company estimated the fair value of the Vivotif and Vaxchora intangible assets using the income approach with a present value discount rate of 14.5% and 15%, respectively, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of PaxVax. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from these intangible assets were based on key assumptions including: estimates of revenues and operating profits; and risks related to the viability of and potential alternative treatments in any future target markets.

The intangible asset associated with IPR&D acquired from PaxVax is related to a product candidate. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was $9.0 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. The Company estimated the fair value using a present value discount rate of 15.5%, which is based on the estimated weighted-average cost of capital for companies with that profiles substantially similar to that of PaxVax and IPR&D assets at a similar stage of development as the product candidate. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value the IPR&D. The projected cash flows for the product candidate was based on key assumptions including: estimates of revenues and operating profits, considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts (see Note 10).

The Company determined the fair value of the inventory using the comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs.

The Company determined the fair value of the property, plant and equipment utilizing either the cost approach or the sales comparison approach. The cost approach is determined by establishing replacement cost of the asset and then subtracting any value that has been lost due to economic obsolescence, functional obsolescence, or physical deterioration. The sales comparison approach determines an asset is equal to the market price of an asset of comparable features such as design, location, size, construction, materials, use, capacity, specification, operational characteristics and other features or descriptions.

The Company recorded approximately $61.6 million in goodwill related to the PaxVax acquisition, calculated as the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired representing the future economic benefits the Company expects to receive as a result of the acquisition. The goodwill created from the PaxVax acquisition is associated with early stage pipeline products along with potential contract manufacturing services. The majority of the goodwill generated from the PaxVax acquisition is expected to be deductible for tax purposes.

The Company has incurred transaction costs related to the PaxVax acquisition of approximately $4.5 million for the year ended December 31, 2018, which have been recorded in selling, general and administrative expenses.

Proforma Financial Information

The following unaudited pro forma information has been presented as if the acquisition of Adapt and Pax Vax occurred on January 1, 2017. The information is based on the historical results of operations of the acquired businesses, adjusted for:

- § the allocation of purchase price and related adjustments, including adjustments to amortization expense related to the fair value of intangible assets acquired;
- § impacts of debt financing, including interest for debt issued and amortization of debt issuance costs;

§ the exclusion of acquisition-related costs incurred during the year-ended December 31, 2018; and
§ associated tax-related impacts of adjustments.

The pro forma results do not necessarily represent what would have occurred if the transactions had taken place on January 1, 2017 nor do they represent the results that may occur in the future. The pro forma adjustments were based on available information and upon assumptions that the Company believes are reasonable to reflect the impact of these acquisitions on the Company's historical financial information on a supplemental pro forma basis. The following table presents the Company's pro forma combined revenues and net income.

(in millions, except per share value)	December 31, 2018	2017
	(Unaudited)	
Revenues	$ 949.3	$ 683.8
Net income	$ 27.7	$ 12.3
Net income per share - basic	$ 0.55	$ 0.29
Net income per share - diluted	$ 0.54	$ 0.28

Acquisition of ACAM2000 business

On October 6, 2017, the Company completed the acquisition of the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) business of Sanofi Pasteur Biologics, LLC ("Sanofi"). This acquisition includes ACAM2000, the only smallpox vaccine licensed by the FDA, a current good manufacturing practices ("cGMP") live viral manufacturing facility and office and warehouse space, both in Canton, Massachusetts, and a cGMP viral fill/finish facility in Rockville, Maryland. With this acquisition, the Company also acquired an existing 10-year contract with the CDC, which expired in March 2018. This contract had a stated value up to $425 million, with a remaining contract value of up to approximately $160 million as of the acquisition date, for the delivery of ACAM2000 to the SNS and establishing U.S.-based manufacturing of ACAM2000. This acquisition added to the Company's product portfolio and expanded the Company's manufacturing capabilities.

At the closing, the Company paid $97.5 million in an upfront payment and $20 million in milestone payments earned as of the closing date tied to the achievement of certain regulatory and manufacturing-related milestones, for a total payment in cash of $117.5 million. The agreement includes an additional milestone payment of up to $7.5 million upon achievement of a regulatory milestone, which was achieved in November 2017. The $7.5 million milestone payment was made during the fourth quarter of 2017. This transaction will be accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of the ACAM2000 business will be recorded as of October 6, 2017, the acquisition date, at their respective fair values, and combined with those of the Company.

The contingent purchase consideration obligation is based on a regulatory milestone. At October 6, 2017, the contingent purchase consideration obligation related to the regulatory milestone was recorded at a fair value of $2.2 million. The Level 3 fair value of this obligation was based on a present value model of management's assessment of the probability of achievement of the regulatory milestone as of the acquisition date. This assessment is based on inputs that have no observable market.

The total purchase price is summarized below:

(in millions)	
Amount of cash paid to Sanofi	$ 117.5
Fair value of contingent purchase consideration	2.2
Total purchase price	$ 119.7

The table below summarizes the allocation of the purchase price based upon the fair values of assets acquired at October 6, 2017. The Company did not assume any liabilities in the acquisition. The Company has finalized the purchase price allocation related to this acquisition.

(in millions)	
Fair value of tangible assets acquired:	
Inventory	$ 74.9
Property, plant and equipment	20.0
Total fair value of tangible assets acquired	94.9
Acquired intangible asset	16.7
Goodwill	8.1
Total purchase price	$ 119.7

The Company determined the fair value of the intangible asset using the income approach, which is based on the present value of future cash flows. The fair value measurements are based on significant unobservable inputs that are developed by the Company using estimates and assumptions of the respective market and market penetration of the Company's products. The Company determined the fair value of the ACAM2000 intangible asset using the income approach with a present value discount rate of 15.50%, based on the estimated weighted-average cost of capital for substantially similar companies. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from ACAM2000 intangible asset were based on key assumptions, including: estimates of revenues and operating profits, the life of the potential commercialized product and associated risks, and risks related to the viability of and potential alternative treatments in any future target markets. The Company has determined the ACAM2000 intangible asset will be amortized over 10 years.

The Company determined the fair value of the inventory using the probability adjusted comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs.

The Company determined the fair value of the property, plant and equipment utilizing either the cost approach or the sales comparison approach. The cost approach is determined based on the replacement cost of the asset and then subtracting any value that has been lost due to economic obsolescence, functional obsolescence, or physical deterioration. The sales comparison approach determines an asset is equal to the market price of an asset of comparable features such as design, location, size, construction, materials, use, capacity, specification, operational characteristics and other features or descriptions.

The Company recorded approximately $8.1 million in goodwill related to the ACAM2000 acquisition, calculated as the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired and represents the future economic benefits the Company expects to receive as a result of the acquisition. Goodwill generated from the ACAM2000 acquisition is not expected to be deductible for tax purposes.

Proforma financial information for the ACAM2000 acquisition has not been included as the financial impact is not material.

Impact of Business Acquisitions

The operations of each of the three business acquisitions discussed above were included in the consolidated financial statements as of each of their respective acquisition dates. The following table presents their revenue and earnings as reported within the consolidated financial statements.

(in millions)	December 31,	December 31,

	2018	2017
Revenue	$ 167.8	$ 11.5
Operating income (loss)	$ 13.4	$ (0.9)

Acquisition of raxibacumab asset

On October 2, 2017, the Company completed the acquisition of raxibacumab, a fully human monoclonal antibody therapeutic product approved by the U.S. Food and Drug Administration ("FDA") for the treatment and prophylaxis of inhalational anthrax, from Human Genome Sciences, Inc. and GlaxoSmithKline LLC (collectively referred to as "GSK"). The all-cash transaction consists of a $76 million upfront payment and up to $20 million in product sale and manufacturing-related milestone payments. The Company recorded an asset (including transaction costs) of $77.6 million, at date of acquisition, which is recorded within intangible assets, net line item of the consolidated balance sheets. None of the milestones have been achieved as of December 31, 2018. The Company has determined that substantially all of the value of raxibacumab is attributed to the raxibacumab asset and therefore the raxibacumab acquisition is considered an asset acquisition.

6. Fair value measurements

The Company's fair value measurement items primarily consist of contingent consideration liabilities that have been generated from our acquisitions. These liabilities represent an obligation of the Company to transfer additional assets to the selling shareholders if future events occur or conditions are met. The Company's contingent consideration is measured initially and subsequently at each reporting date at fair value. The changes in the fair value of contingent consideration obligations are primarily due to the expected amount and timing of future net sales and achieving regulatory milestones, which are inputs that have no observable market (Level 3). Any changes in expectations for the Company's products are classified in the Company's statement of operations as cost of product sales and contract manufacturing. Any changes in expectations for the Company's product candidates are recorded in research and development expense for regulatory and development milestones.

The following table is a reconciliation of the beginning and ending balance of the contingent consideration liabilities measured at fair value using significant unobservable inputs (Level 3) during the years ended December 31, 2018 and 2017.

(in millions)	
Balance at December 31, 2016	$ 13.2
(Income) expense included in earnings	7.8
Settlements	(10.9)
Additions due to acquisition	2.2
Balance at December 31, 2017	$ 12.3
(Income) expense included in earnings	3.1
Settlements	(3.4)
Additions due to acquisition	48.0
Balance at December 31, 2018	$ 60.0

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. As of December 31, 2018 and 2017, there were no assets or liabilities measured at fair value on a non-recurring basis, except for the assets acquired from PaxVax and Adapt, along with the ACAM2000 business. See Note 5. "Acquisitions" for further details on the acquisitions.

7. Inventories

Inventories consist of the following:

	December 31,	
(in millions)	**2018**	**2017**
Raw materials and supplies	$ 51.8	$ 36.1
Work-in-process	103.2	76.6
Finished goods	50.8	30.1
Total inventories	$ 205.8	$ 142.8

The increase in inventories as of December 31, 2018 was primarily due to the acquisition of PaxVax and Adapt in October 2018.

8. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31,	
(in millions)	**2018**	**2017**
Land and improvements	$ 44.6	$ 21.8
Buildings, building improvements and leasehold improvements	216.2	160.0
Furniture and equipment	293.9	206.8
Software	55.2	50.8
Construction-in-progress	71.8	100.2
	681.7	539.6
Less: Accumulated depreciation and amortization	(171.5)	(132.4)
Total property, plant and equipment, net	$ 510.2	$ 407.2

For the year ended December 31, 2018, construction-in-progress primarily includes costs related to manufacturing equipment. For the year ended December 31, 2017, construction-in-progress primarily includes costs related to the build out of the Company's CIADM manufacturing facility.

Depreciation and amortization expense associated with property, plant and equipment was $36.3 million, $32.2 million and $28.0 million for the years ended December 31, 2018, 2017, and 2016, respectively.

9. Intangible assets and goodwill

The Company's intangible assets consist of CBRNE, travelers' and opioid products acquired via business combinations or asset acquisition. Changes in the Company's intangible assets, excluding goodwill and IPR&D, consisted of the following:

(in millions)	Total
Cost basis	
Balance at December 31, 2017	$ 151.4
Additions	667.0
Balance at December 31, 2018	$ 818.4
Accumulated amortization	
Balance at December 31, 2017	$ (31.8)
Amortization	(25.0)
Balance at December 31, 2018	$ (56.8)
Net book value at December 31, 2018	$ 761.6

For the years ended December 31, 2018, 2017, and 2016, the Company recorded amortization expense for intangible assets of $25.0 million, $8.6 million and $7.0 million, respectively, which is included in the amortization of intangible assets line item of the consolidated statements of operations. As of December 31, 2018, the weighted average amortization period remaining for intangible assets is 14.6 years.

Future amortization expense as of December 31, 2018 is as follows:

(in millions)	
2019	$ 57.7
2020	57.6
2021	56.1
2022	53.4
2023 and beyond	536.8
Total remaining amortization	$ 761.6

The following table is a summary of changes in goodwill:

	Year Ended December 31,	
(in millions)	2018	2017
Balance at beginning of the year	$ 49.1	$ 41.0
Additions	210.6	8.1
Balance at end of the year	$ 259.7	$ 49.1

10. Long-term debt

The components of long-term indebtedness are as follows:

	December 31,	
(in millions)	2018	2017
Senior secured credit agreement - Term loan due 2023	$ 447.2	$ -
Senior secured credit agreement - Revolver loan due 2023	348.0	-
2.875% Convertible Senior Notes due 2021	10.6	10.6
Other	3.0	3.0
Total long-term indebtedness	$ 808.8	$ 13.6
Current portion of long-term indebtedness, net of debt issuance costs	(10.1)	-
Unamortized debt issuance costs	(14.2)	(0.1)
Noncurrent portion of long-term indebtedness	$ 784.5	$ 13.5

Senior secured credit agreement

On September 29, 2017, the Company entered into a senior secured credit agreement (the “2017 Credit Agreement”) with four lending financial institutions, which replaced the Company's prior senior secured credit agreement (the "2013 Credit Agreement").

On October 15, 2018, the Company entered into an Amended and Restated Credit Agreement (the "Amended Credit Agreement"), which modified the 2017 Credit Agreement. The Amended Credit Agreement (i) increased the revolving credit facility (the "Revolving Credit Facility") from $200 million to $600 million, (ii) extended the maturity of the Revolving Credit Facility from September 29, 2022 to October 13, 2023, (iii) provided for a term loan in the original principal amount of $450 million (the "Term Loan Facility," and together with the Revolving Credit Facility, the "Senior Secured Credit Facilities"), (iv) added several additional lenders, (v) amended the applicable margin such that borrowings with respect to the Revolving Credit Facility will bear interest at the annual rate described below, (vi) amended the provision relating to incremental credit facilities such that the Company may request one or more incremental term loan facilities, or one or more increases in the commitments under the Revolving Credit Facility (each an "Incremental Loan"), in any amount if, on a pro forma basis, the Company's consolidated secured net leverage ratio does not exceed 2.50 to 1.00 after such incurrence, plus $200 million and (vii) amended the maximum consolidated net leverage ratio financial covenant from 3.50 to 1.0 (subject to 0.50% step up in connection with material acquisitions) to the maximum consolidated net leverage ratio described below.

In October 2018, the Company borrowed $318 million under the Revolving Credit Facility and $450 million under the Term Loan Facility to finance a portion of the consideration for the PaxVax and Adapt acquisitions and related expenses.

For the years ended December 31, 2018 and 2017, we capitalized debt issuance costs of $13.4 million and $1.4 million, as a direct reduction to the Term Loan and the revolver, respectively.

Borrowings under the Revolving Credit Facility and the Term Loan Facility will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.00% per annum, depending on the Company's consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a eurocurrency rate for an interest period of one month plus 1%) plus a margin ranging from 0.25% to 1.00%, depending on the Company's consolidated net leverage ratio. The Company is required to make quarterly payments under the Amended Credit Agreement for accrued and unpaid interest on the outstanding principal balance, based on the above interest rates. In addition, the Company is required to pay commitment fees ranging from 0.15% to 0.30% per annum, depending on the Company's consolidated net leverage ratio, in respect of the average daily

unused commitments under the Revolving Credit Facility. The Company is to repay the outstanding principal amount of the Term Loan Facility in quarterly installments based on an annual percentage equal to 2.5% of the original principal amount of the Term Loan Facility during each of the first two years of the Term Loan Facility, 5% of the original principal amount of the Term Loan Facility during the third year of the Term Loan Facility and 7.5% of the original principal amount of the Term Loan Facility during each year of the remainder of the term of the Term Loan Facility until the maturity date of the Term Loan Facility, at which time the entire unpaid principal balance of the Term Loan Facility will be due and payable. The Company has the right to prepay the Term Loan Facility without premium or penalty. The Revolving Credit Facility and the Term Loan Facility mature (unless earlier terminated) on October 13, 2023.

The Amended Credit Agreement also requires mandatory prepayments of the Term Loan Facility in the event the Company or its Subsidiaries (a) incur indebtedness not otherwise permitted under the Amended Credit Agreement or (b) receive cash proceeds in excess of $100 million during the term of the Amended Credit Agreement from certain dispositions of property or from casualty events involving their property, subject to certain reinvestment rights.

The Amended Credit Agreement contains affirmative and negative covenants customary for financings of this type. Negative covenants in the Amended Credit Agreement, among other things, limit the ability of the Company to: incur indebtedness and liens; dispose of assets; make investments including loans, advances, guarantees, or acquisitions (other than permitted acquisitions, subject to compliance with the financial covenants and certain other conditions); and enter into certain merger or consolidation transactions. The Amended Credit Agreement also contains financial covenants, including (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, and (2) a maximum consolidated net leverage ratio of 4.00 to 1.00 through September 29, 2019, 3.75 to 1.00 from September 30, 2019 through September 29, 2020 and 3.50 to 1.00 thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition, subject to the terms and conditions of the Amended Credit Agreement. Each of the ratios referred to in the foregoing clauses (1) and (2) is calculated on a consolidated basis for each consecutive four fiscal quarter period. As of December 31, 2018, the Company is in compliance with affirmative and negative covenants.

2.875% Convertible senior notes due 2021

On January 29, 2014, the Company issued $250.0 million aggregate principal amount of 2.875% Convertible Senior Notes due 2021 (the "Notes"). The Notes bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year. The Notes mature on January 15, 2021, unless earlier purchased by the Company or converted. The original conversion rate is equal to 30.8821 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $32.38 per share of common stock). The conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. The Company incurred approximately $8.3 million in debt issuance costs associated with the Notes, which has been capitalized on the consolidated balance sheets and is being amortized over seven years. As of August 1, 2016, certain conversion features were triggered due to the completion of the Aptevo spin-off. The conversion rate under the Notes was adjusted in accordance with the terms of the indenture. Effective August 12, 2016, the conversion rate was adjusted to 32.3860 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $30.88 per share of common stock).

On November 14, 2017, the Company issued a notice of termination of conversion rights for its outstanding Notes, of which $250.0 million was outstanding as of the notice date. In connection with the notice of termination, bondholders were given the option to convert their notes into the Company's stock at a rate of 32.386 per $1,000 of principal outstanding, plus a make-whole of an additional 3.1556 shares per $1,000 principal outstanding, in accordance with the terms of the indenture. The Company was not obligated to pay accrued or unpaid interest on converted notes, and bondholders who did not convert by the deadline of December 28, 2017 would retain their bonds but lose the conversion rights associated with the Notes and be paid interest of 2.875% until the earlier of maturity of the Notes in 2021 or the bonds being called and repaid in full by the Company. Between July 15, 2017 and the notification of termination of conversion rights, the Company accrued interest on the converted Notes of $2.4 million which was recorded as an increase in additional paid-in-capital on the balance sheet. Between November 14, 2017 and December 28, 2017 (the "conversion period"), approximately $239.4 million of bonds were converted into 8.5 million shares of the Company's common stock, inclusive of shares issued as part of the make-whole provision. In addition, the Company recorded a reduction in additional paid-in-capital on the Company's balance sheet of $3.6 million associated with debt issuance costs attributable to the converted notes. After giving effect to the converted bonds, the outstanding principal balance of the Notes as of December 31, 2018 was $10.6 million.

Future debt payments of long-term indebtedness are as follows:

(in millions)	December 31, 2018
2019	$ 11.3
2020	14.1
2021	35.9
2022	33.8
2023 and thereafter	713.7
Total long-term indebtedness	$ 808.8

11. Stockholders' equity

Preferred stock

The Company is authorized to issue up to 15.0 million shares of preferred stock, $0.001 par value per share ("Preferred Stock"). Any Preferred Stock issued may have dividend rights, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company's board of directors.

Common stock

The Company currently has one class of common stock, $0.001 par value per share common stock ("Common Stock"), authorized and outstanding. The Company is authorized to issue up to 200.0 million shares of Common Stock. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters, except as may be provided by law.

Accounting for stock-based compensation

The Company has one stock-based employee compensation plan, the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "Emergent Plan"), which includes both stock options and restricted stock units.

As of December 31, 2018, an aggregate of 21.9 million shares of common stock were authorized for issuance under the Emergent Plan, of which a total of approximately 3.8 million shares of common stock remain available for future awards to be made to plan participants. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Awards granted under the Emergent Plan have a contractual life of no more than 10 years.

The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. Set forth below are the assumptions used in valuing the stock options granted:

	Year Ended December 31,		
	2018	**2017**	**2016**
Expected dividend yield	0%	0%	0%
Expected volatility	38-39%	37-40%	31-33%
Risk-free interest rate	2.54-3.03%	1.66-1.88%	0.93-1.22%

Expected average life of options	4.5 years	4.3 years	4.3 years

Stock options and restricted stock units

The following is a summary of stock option award activity under the Emergent Plan:

	Emergent Plan		
(in millions, except share and per share data)	**Number of Shares**	**Weighted-Average Exercise Price**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2017	2,121,405	$ 25.48	$ 44.5
Granted	460,902	51.39	
Exercised	(665,183)	21.36	
Forfeited	(45,656)	33.14	
Outstanding at December 31, 2018	1,871,468	$ 32.59	$ 50.1
Exercisable at December 31, 2018	1,081,513	$ 26.13	$ 35.9
Options expected to vest at December 31, 2018	696,083	$ 41.10	$ 12.8

The following is a summary of restricted stock unit award activity under the Emergent Plan:

(in millions, except share and per share data)	**Number of Shares**	**Weighted-Average Grant Price**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2017	851,720	$ 30.84	$ 39.6
Granted	557,767	52.70	
Vested	(427,610)	30.12	
Forfeited	(60,784)	38.77	
Outstanding at December 31, 2018	921,093	$ 42.82	$ 54.6

The weighted average remaining contractual term of options outstanding as of December 31, 2018 and 2017 was 4.0 years and 4.0 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2018 and 2017 was 3.0 years and 3.2 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2018, 2017, and 2016 was $18.48, $10.53 and $9.24 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2018, 2017, and 2016 was $24.4 million, $13.9 million and $15.6 million, respectively. The total fair value of awards vested during 2018, 2017 and 2016 was $16.9 million, $17.9 million and $16.9 million, respectively. As of the year ended December 31, 2018, the total compensation cost and weighted average period over which total compensation is expected to be recognized related to unvested equity awards was $32.8 million and 2.2 years, respectively.

Stock-based compensation expense was recorded in the following financial statement line items:

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Cost of product sales	$ 1.7	$ 1.1	$ 1.0
Research and development	3.1	2.5	2.3
Selling, general and administrative	18.4	11.6	14.1
Continuing operations	23.2	15.2	17.4
Discontinued operations	-	-	1.1
Total stock-based compensation expense	$ 23.2	$ 15.2	$ 18.5

Share Repurchase Program

In March 2018, the Company's board of directors authorized management to repurchase, from time to time, up to an aggregate of $ million of the Company's common stock under a board-approved share repurchase program. The term of the board authorization of the repurchase program is until December 31, 2019. Any repurchased shares will be available for use in connection with the Company's stock plans and for other corporate purposes. As of December 31, 2018, the Company has not repurchased any shares under this program.

12. Income taxes

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The legislation significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, implementing a territorial tax system and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018.

The Company uses the asset and liability method of accounting for income taxes. Under this 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. 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 reverse. Valuation allowances are recorded as appropriate to reduce deferred tax assets to the amount considered likely to be realized. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the Tax Reform Act, the Company revalued its ending net deferred tax liabilities in the United States at December 31, 2017 and recognized a provisional $13.4 million tax benefit in the Company's consolidated statement of income for the year ended December 31, 2017. During 2018 we adjusted the provisional estimate by approximately $4.5 million, bringing the total tax benefit recorded to date to $17.9 million related to the revaluation of our deferred tax assets and liabilities.

The Tax Reform Act provided for a one-time deemed mandatory repatriation of post-1986 undistributed foreign subsidiary earnings and profits ("E&P") through the year ended December 31, 2017. The Company had an estimated $95.4 million of undistributed foreign E&P subject to the deemed mandatory repatriation and recognized a provisional transition tax of $13.6 million of income tax expense in the Company's consolidated statement of income for the year ended December 31, 2017. During 2018 we reduced the provisional transition tax by $0.2 million, bringing the total transition tax to $13.4 million. The Company has elected to pay U.S. federal cash taxes on the deemed mandatory repatriation over eight years.

While the Tax Reform Act provides for a territorial tax system, beginning in 2018, it includes two new U.S. tax base erosion provisions, the global intangible low-taxed income ("GILTI") provisions and the base-erosion and anti-abuse tax ("BEAT") provisions.

The GILTI provisions require the Company to include in its U.S. income tax return foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets. The Company is subject to incremental U.S. tax on GILTI income beginning in 2018. The Company has elected to

account for GILTI tax in the period in which it is incurred, and therefore has not provided any deferred tax impacts of GILTI in its consolidated financial statements for the year ended December 31, 2018.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. The Company recognized the provisional tax impacts related to deemed repatriated earnings and the revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. During 2018, the Company completed the analysis of The Tax Reform Act's income tax effects based on legislative updates relating to the Act currently available. This resulted in an additional SAB 118 tax benefit of $ million in the third quarter of 2018 related to an adjustment to the transition tax and the remeasurement of certain deferred tax assets and liabilities upon the filing of the 2017 U.S. corporate income tax return.

Significant components of the provisions for income taxes attributable to operations consist of the following:

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Current			
Federal	$ 1.8	$ 29.4	$ 29.2
State	2.4	3.0	2.3
International	6.0	0.3	1.0
Total current	10.2	32.7	32.5
Deferred			
Federal	7.5	(6.0)	10.0
State	3.0	(0.6)	(0.2)
International	(1.9)	9.9	(5.6)
Total deferred	8.6	3.3	4.2
Total provision for income taxes	$ 18.8	$ 36.0	$ 36.7

The Company's net deferred tax asset (liability) consists of the following:

	December 31,	
(in millions)	**2018**	**2017**
Federal losses carryforward	$ 10.7	$ 1.6
State losses carryforward	18.1	17.2
Research and development carryforward	10.1	3.5
State research and development carryforward	5.0	-
Scientific research and experimental development credit carryforward	13.1	16.5
Stock compensation	7.5	5.3
Foreign NOLs	35.4	34.1
Deferred revenue	11.6	-
Inventory reserves	3.4	1.6
Other	4.9	3.9
Deferred tax asset	119.8	83.7
Fixed assets	(46.4)	(23.1)
Intangible assets	(60.4)	(2.2)
Other	(0.7)	(10.5)
Deferred tax liability	(107.5)	(35.8)
Valuation allowance	(66.4)	(45.1)
Net deferred tax asset (liability)	$ (54.1)	$ 2.8

As of December 31, 2018, the Company has a net U.S. deferred tax liability in the amount of $4.8 million and a foreign net deferred tax liability in the amount of $49.3 million. The Company had a net U.S. deferred tax liability in the amount of $13.1 million and a foreign net deferred tax asset in the amount of $15.9 million as of December 31, 2017.

As of December 31, 2018, the Company currently has approximately $50.7 million ($10.6 million tax effected) in U.S federal net operating loss carryforwards along with $14.1 million in research and development tax credit carryforwards for U.S. federal and state tax purposes that will begin to expire in 2027 and 2024, respectively. The U.S. federal net operating loss carryforwards are recorded with a $24.3 million valuation allowance. The research and development tax credit carryforwards have a valuation allowance in the amount of $9.6 million. The Company has $280.4 million ($18.1 million tax effected) in state net operating loss carryforwards, primarily in Maryland and California, that will begin to expire in 2019. The U.S. state tax loss carryforwards are recorded with a valuation allowance of $245.9 million ($16.4 million tax effected). The Company has approximately $192.6 million ($35.4 million tax effected) in net operating losses from foreign jurisdictions that will have an indefinite life unless the foreign entities have a change in the nature or conduct of the business in the three years following a change in ownership. A valuation allowance in respect to these foreign losses has been recorded in the tax effected amount of $35.5 million. The Company currently has approximately $13.2 million in Manitoba scientific research and experimental development credit carryforwards that will begin to expire in 2026. The use of any of these net operating losses and research and development tax credit carryforwards may be restricted due to future changes in the Company's ownership.

The provision for income taxes differs from the amount of taxes determined by applying the U.S. federal statutory rate to income before the provision for income taxes as a result of the following:

	Year ended December 31,		
(in millions)	**2018**	**2017**	**2016**
US	$ 71.0	$ 80.7	$ 63.3
International	10.5	37.9	35.9
Earnings before taxes on income	81.5	118.6	99.2
Federal tax at statutory rates	$ 17.1	$ 41.5	$ 34.7
State taxes, net of federal benefit	4.3	1.3	0.5
Impact of foreign operations	2.8	(2.2)	(9.9)
Change in valuation allowance	(0.1)	0.3	10.5
Tax credits	(1.8)	(1.9)	(1.6)

Transition tax	(0.2)	13.6	-
Change in U.S. tax rate	(4.5)	(13.4)	-
Stock compensation	(5.8)	(4.0)	-
Other differences	(0.9)	0.4	(0.6)
Return to provision true-ups	1.1	(0.5)	1.7
Transaction costs	5.4	-	-
GILTI, net	0.4	-	-
Permanent differences	1.0	0.9	1.4
Provision for income taxes	$ 18.8	$ 36.0	$ 36.7

The effective annual tax rate for the years ended December 31, 2018, 2017, and 2016 was 23%, 30% and 37%, respectively.

The effective annual tax rate of 23% in 2018 is higher than the statutory rate primarily due to the impact of state taxes, GILTI, acquisition transaction costs and other non-deductible items, and the jurisdictional mix of earnings. This is partially offset by the impact of the SAB 118 benefit and the stock option deduction benefit.

The effective annual tax rate of 30% in 2017 differs from statutory rate primarily due to the jurisdictional mix of earnings. Due to the impact of the Tax Reform Act enacted on December 22, 2017, the Company recognized a $13.4 million tax benefit as a result of revaluing the U.S. ending net deferred tax liabilities from 35% to the newly enacted U.S. corporate income tax rate of 21%. The tax benefit was fully offset by tax expense of $13.6 million for the transition tax on the deemed mandatory repatriation of undistributed earnings.

The increase in the effective annual tax rate in 2016 was primarily related to tax on the sale, within the Company's consolidated group, of assets from Canadian subsidiaries to U.S. subsidiaries in preparation of the spin-off of Aptevo, and a valuation allowance charge recorded in its continuing operations related to Aptevo deferred tax assets prior to the distribution. The Company determined that upon spin-off, the deferred tax assets of Aptevo would be unrealizable.

The Company recognizes interest in interest expense and recognizes potential penalties related to unrecognized tax benefits in selling, general and administrative expense. Of the total unrecognized tax benefits recorded at December 31, 2018 and 2017, $0.4 million and $0.8 million, respectively, is classified as a current liability and $8.4 million and $1.2 million, respectively, is classified as a non-current liability on the balance sheet.

The table below presents the gross unrecognized tax benefits activity for 2018, 2017 and 2016:

(in millions)	
Gross unrecognized tax benefits at December 31, 2015	$ 1.5
Increases for tax positions for prior years	-
Decreases for tax positions for prior years	-
Increases for tax positions for current year	0.3
Settlements	-
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2016	1.8
Increases for tax positions for prior years	-
Decreases for tax positions for prior years	-
Increases for tax positions for current year	0.5
Settlements	(0.3)
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2017	2.0
Increases for tax positions for prior years	-
Unrecognized tax benefits acquired in business combinations	6.5
Decreases for tax positions for prior years	-
Increases for tax positions for current year	0.3
Settlements	-
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2018	$ 8.8

The increase in the gross unrecognized tax benefit in the amount of $6.5 million relating to the acquisition of PaxVax is entirely offset by a receivable pursuant to a Tax Indemnity Agreement that became effective as at the close of the acquisition.

When resolved, substantially all of these reserves would impact the effective tax rate.

The Company's federal and state income tax returns for the tax years 2013 to 2017 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2010 to 2017, and tax returns in Germany remain open indefinitely. The Company's tax returns for Canada remain open to examination for the tax years 2011 to 2017.

As of December 31, 2018, the Company's Canadian 2017 Scientific Research and Experimental Development Claim is under audit. As of December 31, 2018, the Company's 2013 and 2014 federal income tax returns are under audit.

13. Defined benefit and 401(k) savings plan

Defined benefit plan

The Company sponsors a defined benefit pension plan as assumed through the acquisition of PaxVax covering eligible employees in Switzerland (the "Swiss Plan"). Under the Swiss Plan, the Company and certain of its employees with annual earnings in excess of government determined amounts are required to make contributions into a fund managed by an independent investment fiduciary. Employer contributions must be in an amount at least equal to the employee's contribution. The Swiss Plan assets are comprised of an insurance contract that has a fair value consistent with its contract value based on the practicability exception using level 3 inputs. The entire liability is listed as non-current, because plan assets are greater than the expected benefit payments over the next year. The Company recognized pension expense related to the Swiss Plan of $0.3 million reflected as a component of selling, general and administrative for the year ended December 31, 2018.

The funded status of the Swiss Plan is as follows:

(in millions)	**December 31,** 2018
Fair value of plan assets, beginning of year	$ —

Acquisitions	18.2
Employer contributions	0.2
Employee contributions	0.1
Benefits paid	0.3
Actual administration expenses	—
Actual return on plan assets	—
Settlements	(0.6)
Currency impact	—
Fair value of plan assets, end of year	18.2
Projected Benefit Obligation, beginning of year	$ —
Acquisitions	28.3
Service cost	0.3
Interest Cost	0.1
Employee contributions	0.1
Actuarial loss	0.3
Benefits paid (refunded)	(0.1)
Actual administration expenses, taxes	—
Plan amendment	0.1
Settlements	(0.6)
Currency impact	0.1
Projected benefit obligation, end of year	$ 28.6
Funded status, end of year	$ (10.4)
Accumulated benefit obligation, end of year	$ 25.6

Since assets exceed the present value of expected benefit payments for the next twelve months, all of the liability is noncurrent.

Components of net periodic pension cost incurred during the year are as follows:

(in millions)	**December 31,** 2018
Service cost	$ 0.3
Interest cost	0.1
Expected return on plan assets	(0.1)
Amortization of loss	—
Amortization of prior service cost	—
Net periodic benefit cost	$ 0.3

The weighted average assumptions used to calculate the projected benefit obligations are as follows:

	December 31, 2018
Discount rate	0.9%
Expected rate of return	3.0%
Rate of future compensation increases	1.5%

The overall expected long-term rate of return on assets assumption considers historical returns, as well as expected future returns based on the fact that investment returns are insured, and the legal minimum interest crediting rate as applicable. Total contributions expected to be made into the plan for the year-ended December 31, 2019 is $1.0 million.

The following table presents losses recognized in accumulated other comprehensive loss before income tax related to the Company's defined benefit pension plans:

(in millions)	**Year Ended December 31,** 2018
Net actuarial loss	$ 0.1
Prior service cost	0.1
Total recognized in accumulated other comprehensive loss	$ 0.2

Actuarial losses in accumulated other comprehensive loss related to the Company's defined benefit pension plans expected to be recognized as components of net periodic benefit cost over the year ending December 31, 2019 are de minimis.

Future benefits expected to be paid as of December 31, 2018 are as follows:

(In millions)	December 31, 2018
2019	$ 1.0
2020	2.0
2021	0.8
2022	1.4
2023	0.9
Thereafter	5.8
Total	$ 11.9

401(k) savings plan

The Company has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers substantially all U.S. employees. Under the 401(k) Plan, employees may make elective salary deferrals. During the year ended December 31, 2018, the Company made matching contributions of approximately $3.1 million, which includes our acquisitions of Adapt and PaxVax. During the years ended December 31, 2017 and 2016, the Company made matching contributions of approximately $2.7 million and $2.5 million, respectively.

14. Leases

The Company leases fill/finish, manufacturing, laboratory, warehouse and office facilities, office equipment and vehicles under various operating lease agreements to operate its business. For the years ended December 31, 2018, 2017, and 2016, total lease expense was $3.3 million, $1.6 million and $1.4 million, respectively.

Future minimum lease payments under operating lease obligations as of December 31, 2018 were as follows:

(in millions)	
2019	$ 3.4
2020	2.5
2021	2.5
2022	2.0
2023	2.6
2024 and beyond	2.5
Total minimum lease payments	$ 15.5

15. Earnings per share

The following table presents the calculation of basic and diluted net income per share:

	Year ended December 31,		
(in millions, except per share data)	**2018**	**2017**	**2016**
Numerator:			
Net income from continuing operations	$ 62.7	$ 82.6	$ 62.5
Interest expense, net of tax	-	2.6	3.3
Amortization of debt issuance costs, net of tax	-	0.7	0.8
Net income, adjusted from continuing operations	62.7	85.9	66.6
Net loss from discontinued operations	-	-	(10.7)
Net income, adjusted	$ 62.7	$ 85.9	$ 55.9
Denominator:			
Weighted-average number of shares-basic	50.1	41.8	40.2
Dilutive securities-equity awards	1.3	1.1	1.0
Dilutive securities-convertible debt	-	7.4	8.1
Weighted-average number of shares-diluted	51.4	50.3	49.3
Net income per share-basic from continuing operations	$ 1.25	$ 1.98	$ 1.56
Net loss per share-basic from discontinued operations	-	-	(0.27)
Net income per share-basic	$ 1.25	$ 1.98	$ 1.29
Net income per share-diluted from continuing operations	$ 1.22	$ 1.71	$ 1.35
Net loss per share-diluted from discontinued operations	-	-	(0.22)
Net income per share-diluted	$ 1.22	$ 1.71	$ 1.13

For the year ending December 31, 2018 and 2017, substantially all of the outstanding stock options to purchase shares of common stock were included in the calculation of diluted earnings per share. For the years ending December 31, 2016, outstanding stock options to purchase approximately 1.4 million shares of common stock, respectively, are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year and their effect would be anti-dilutive.

16. Purchase commitment

As of December 31, 2018 the Company has approximately $66.7 million of purchase commitments associated with raw materials and contract manufacturing services that will be purchased in the next three years. For the years ended December 31, 2018, 2017, and 2016, the Company purchased $12.1 million, $3.0 million and $4.5 million, respectively, of materials under this commitment.

17. Segment information

For financial reporting purposes, the Company reports financial information for one reportable segment. This reportable segment engages in business activities based on financial information that is provided to and resources which are allocated by the Chief Operating Decision Maker. The accounting policies of the reportable segment is the same as those described in the summary of significant accounting policies.

For the year ended December 31, 2018, 2017 and 2016, the Company's revenues disaggregated by the major sources was as follows:

(in millions)	**Year Ended December 31,**								
	2018			**2017**			**2016**		
	U.S Government	**Non-U.S. Government**	**Total**	**U.S Government**	**Non-U.S. Government**	**Total**	**U.S Government**	**Non-U.S. Government**	**Total**
Product sales	$ 526.1	$ 80.4	$ 606.5	$ 374.8	$ 46.7	$ 421.5	$ 283.2	$ 13.1	$ 296.3
Contract manufacturing	-	98.9	98.9	-	68.9	68.9	-	49.1	49.1

Contracts and grants	71.5	5.5	77.0	65.1	5.4	70.5	138.1	5.3	143.4
Total revenues	$ 597.6	$ 184.8	$ 782.4	$ 439.9	$ 121.0	$ 560.9	$ 421.3	$ 67.5	$ 488.8

For the years ended December 31, 2018, 2017, and 2016, the Company's revenues within the United States comprised 91%, 89% and 94%, respectively, of total revenues. For the years ended December 31, 2018, 2017, and 2016, product sales from BioThrax to the USG comprised approximately 45%, 67% and 80%, respectively, of total product sales.

The Company's product sales from BioThrax, ACAM2000 and Other comprised approximately:

	2018	2017	2016
% of product sales:			
BioThrax	46%	68%	80%
ACAM2000	19%	0%	0%
Other	35%	32%	20%

As of December 31, 2018, 2017 and 2016, aside from BioThrax and ACAM2000, there were no other product sales to an individual customer or for an individual product in excess of 10% of total revenues.

For years ended December 31, 2018 and 2017, the Company had long-lived assets outside of the United States of approximately $82.9 million and $28.6 million, respectively, which are primarily located within Canada and Switzerland.

18. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2018 and 2017 is presented in the following tables:

	Quarter Ended			
(in millions, except per share data)	**March 31,**	**June 30,**	**September 30,**	**December 31,**
2018:				
Revenue	$ 117.8	$ 220.2	$ 173.7	$ 270.7
Income (loss) from operations	(9.5)	66.8	21.3	11.2
Net income (loss)	(4.9)	50.1	20.9	(3.4)
Net income (loss) per share-basic	$ (0.10)	$ 1.00	$ 0.42	$ (0.07)
Net income (loss) per share-diluted	$ (0.10)	$ 0.98	$ 0.41	$ (0.07)
2017:				
Revenue	$ 116.9	$ 100.8	$ 149.4	$ 193.8
Income from operations	14.9	8.5	47.8	53.1
Net income	10.5	4.6	33.6	33.9
Net income per share-basic	$ 0.26	$ 0.11	$ 0.81	$ 0.77
Net income per share-diluted	$ 0.23	$ 0.11	$ 0.68	$ 0.67

19. Litigation

ANDA Litigation

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd., or collectively, Adapt Pharma, and Opiant Pharmaceuticals, Inc., or Opiant, received notice from Perrigo UK FINCO Limited Partnership, or Perrigo, that Perrigo had filed an Abbreviated New Drug Application, or ANDA, with the United States Food and Drug Administration, or FDA, seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, or the '253 Patent, 9,468,747, or the '747 Patent, 9,561,177, or the '177 Patent, 9,629,965, or the '965 Patent, and 9,775,838, or the '838 Patent. On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937, or the '937 Patent. Perrigo's notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries and Opiant, or collectively, Plaintiffs, filed a complaint for patent infringement of the '253, '747, '177, '965, and the '838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the '937 Patent. As a result of timely filing the first lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the Court.

On or about February 27, 2018, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva Pharmaceuticals Industries Ltd. and Teva Pharmaceuticals USA, Inc., or collectively Teva, that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2 mg/spray before the expiration of U.S. Patent No. 9,480,644, or the '644 Patent, and U.S. Patent No. 9,707,226, or the '226 Patent. Teva's notice letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey.

On or about September 13, 2016, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration of U.S. Patent No. 9,211,253, or the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the '747, the '177, the '965, the '838, and the '937 Patents. Teva's notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '253, the '747, the '177, the '965, the '838, or the '937 Patent, or that the '253, the '747, the '177, the '965, the '838, and the '937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings have been consolidated. As of February 21, 2019, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, are evaluating Teva's notice letter related to the '937 Patent.

In the complaints described in the paragraphs above, the Plaintiffs seek, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo's respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court.

As of the date of this filing, the range of potential gain cannot be determined or estimated for the above mentioned complaints.

Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn ("Sponn"), filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive (the "Class Period"), seeking to pursue remedies under the Exchange Act against the Company and certain of its senior officers and directors (collectively, the "Defendants"). The complaint alleged, among other things, that the Defendants made materially false and misleading statements about the government's demand for BioThrax and expectations that the Company's five-year exclusive procurement contract with HHS would be renewed, and omitted certain material facts. Sponn sought unspecified damages, including legal costs. On October 25, 2016, the court added City of Cape Coral Municipal Firefighters' Retirement Plan and City of Sunrise Police Officers' Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robbins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Plaintiffs filed an amended complaint that cited the same class period, named the same defendants and made similar allegations to the original complaint. The Defendants filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Defendants' Motion to Dismiss was heard and denied on July 6, 2017. The Defendants filed an answer on July 28, 2017. The parties then engaged in the process of exchanging discovery. The Plaintiffs filed an amended motion for class certification and appointment of Lead Plaintiffs, Sponn, and Geoffrey L. Flagstad ("Flagstad") as Class Representatives on December 20, 2017. A hearing on that motion was heard on May 2, 2018. On June 8, 2018 the Court granted class certification with a shortened class period, May 5, 2016 to June 21, 2016. In that same order, the court appointed Flagstad as Class Representative and Robbins Geller Rudman & Dowd LLP as Class Counsel. The Defendants have denied, and continue to deny, any and all allegations of fault, liability, wrongdoing, or damages. However, recognizing the risk, time, and expense of litigating any case to trial, on August 27, 2018, the Defendants reached an agreement in principle with Plaintiffs to settle all of the related claims of any individual plaintiff that purchased or acquired Company stock from January 11, 2016 to June 21, 2016, for $6.5 million, an amount that was paid by the Company's insurance carrier. The settlement required no payment by any of the Defendants. The Defendants continue to deny any and all liability. The parties executed the settlement agreement on October 16, 2018 and filed the agreement with the court on October 17, 2018. The court granted preliminary approval of the settlement on October 18, 2018, issued an amended preliminary approval of the settlement on October 25, 2018, and scheduled a hearing regarding final approval for January 22, 2019. At the time of the final approval hearing on January 22, 2019, there were no objections to the settlement, but there were two shareholders who had submitted opt-outs so that they could be excluded from the settlement. On January 25, 2019, the court issued an order and final judgment approving the settlement. Although the court has approved the settlement, the court's decision can be appealed for a period of time. In addition, the shareholders who opted out could try to bring their own claims. The Company, therefore, at this time, cannot predict the results of this lawsuit and possible other legal proceedings with certainty. Defendants continue to believe that the allegations in the complaint are without merit. As of the date of this filing, the range of potential loss cannot be determined or estimated.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2018, our internal control over financial reporting was effective based on those criteria.

Management's assessment of and conclusion on the effectiveness of disclosure controls and procedures and internal controls over financial reporting did not include the internal controls related to the operations acquired in the acquisition of PaxVax Holding Company Ltd. ("PaxVax") and Adapt Pharma Limited ("Adapt") which are included in the 2018 consolidated financial statements of Emergent BioSolutions, Inc. and subsidiaries and constituted $1.1 billion and $942.0 million of total and net assets, respectively, as of December 31, 2018 and $51.1 million and $28.7 million of revenues and operating loss, respectively, for the year then ended. Our audit of internal control over financial reporting of Emergent BioSolutions Inc. and subsidiaries also did not include an evaluation of the internal control over financial reporting of PaxVax and Adapt.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2018, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f)) identified in connection with the evaluation required by Rule 13a-15(d) of the Exchange Act that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Emergent BioSolutions Inc. and subsidiaries

Opinion on Internal Control over Financial Reporting

We have audited Emergent BioSolutions Inc. and subsidiaries' internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Emergent BioSolutions Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018 based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of PaxVax Holding Company Ltd. (PaxVax) or Adapt Pharma Limited (Adapt), which are included in the 2018 consolidated financial statements of the Company, and constituted $1.1 billion and $942.0 million of total and net assets, respectively, as of December 31, 2018 and $51.1 million and $28.7 million of revenues and operating loss, respectively, for the year then

ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of PaxVax or Adapt.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15 and our report dated February 21, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Baltimore, Maryland
February 21, 2019

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Code of Ethics

We have adopted a code of business conduct and ethics that applies to our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), as well as our other employees. A copy of our code of business conduct and ethics is available on our website at www.emergentbiosolutions.com. We intend to post on our website all disclosures that are required by applicable law, the rules of the Securities and Exchange Commission or the New York Stock Exchange concerning any amendment to, or waiver of, our code of business conduct and ethics.

The remaining information required by Item 10 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2019 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2019 annual meeting of stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by Item 12 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2019 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by Item 13 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2019 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2019 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

The following financial statements and supplementary data are filed as a part of this annual report on Form 10-K in Part I, Item 8.

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets at December 31, 2018 and 2017
Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016
Consolidated Statements of Comprehensive Income for the years ended December 31, 2018, 2017 and 2016
Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016
Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016
Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II - Valuation and Qualifying Accounts for the years ended December 31, 2018, 2017 and 2016 has been filed as part of this annual report on Form 10-K. All other financial statement schedules are omitted because they are not applicable or the required information is included in the financial statements or notes thereto.

Exhibits

Those exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately preceding the exhibits hereto and such listing is incorporated herein by reference.

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

(in millions)	Beginning Balance	Charged to costs and expenses	Deductions	Ending Balance
Year Ended December 31, 2018				
Inventory allowance	$ 3.8	$ 14.6	$ (8.8)	$ 9.6
Prepaid expenses and other current assets allowance	5.3	-	(1.0)	4.3
Year Ended December 31, 2017				
Inventory allowance	$ 3.5	$ 8.8	$ (8.5)	$ 3.8
Prepaid expenses and other current assets allowance	4.9	0.4	-	5.3
Year Ended December 31, 2016				
Inventory allowance	$ 1.6	$ 10.0	$ (8.1)	$ 3.5
Prepaid expenses and other current assets allowance	2.0	2.9	-	4.9

Exhibit Index

All documents referenced below were filed pursuant to the Securities Exchange Act of 1934 by the Company, (File No. 001-33137), unless otherwise indicated.

Exhibit Number		Description
2.1		Contribution Agreement, dated July 29, 2016, by and among Emergent BioSolutions Inc., Aptevo Therapeutics Inc., Aptevo Research and Development LLC and Aptevo BioTherapeutics LLC (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed on August 4, 2016).
2.2		Separation and Distribution Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc. (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K, filed on August 4, 2016).
2.3		Asset Purchase Agreement, dated July 14, 2017, among Sanofi Pasteur Biologics, LLC, Acambis Research Ltd. and Emergent BioSolutions Inc. (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on July 14, 2017).
2.4		Asset Purchase Agreement, dated July 19, 2017, among GlaxoSmithKline LLC, Human Genome Sciences, Inc., and Emergent BioSolutions Inc. (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on October 3, 2017).
2.5	†	Merger Agreement, dated August 8, 2018, by and among Emergent BioSolutions Inc., PaxVax Holding Company Ltd., Panama Merger Sub Ltd., and PaxVax SH Representative LLC (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on October 5, 2018).
2.6	†	Share Purchase Agreement, dated August 28, 2018, by and among Emergent BioSolutions Inc., the Sellers identified therein, Seamus Mulligan and Adapt Pharma Limited (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on October 15, 2018).
3.1		Third Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).
3.2		Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3 to the Company's Current Report on Form 8-K filed on August 16, 2012).
4.1		Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Company's Registration Statement on Form S-1 filed on October 20, 2006) (Registration No. 333-136622).
4.2		Registration Rights Agreement, dated as of September 22, 2006, among the Company and the stockholders listed on Schedule 1 thereto (incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on September 25, 2006) (Registration No. 333-136622).
4.3		Indenture, dated as of January 29, 2014, between the Company and Wells Fargo Bank, National Association, including the form of 2.875% Convertible Senior Notes due 2021 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 29, 2014).
9.1		Voting and Right of First Refusal Agreement, dated as of October 21, 2005, between the William J. Crowe, Jr. Revocable Living Trust and Fuad El-Hibri (incorporated by reference to Exhibit 9.1 to the Company's Registration Statement on Form S-1 filed on August 14, 2006) (Registration No. 333-136622).
10.1		Credit Agreement, dated September 29, 2017, among Emergent BioSolutions Inc., the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed on October 2, 2017).
10.2		Amended and Restated Credit Agreement, dated October 15, 2018, by and among Emergent BioSolutions Inc., the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed on October 15, 2018).
10.3	*	Emergent BioSolutions Inc. Employee Stock Option Plan, as amended and restated on January 26, 2005 (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on August 14, 2006) (Registration No. 333-136622).
10.4	*	Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 5 to the Company's Registration Statement on Form S-1 filed on October 30, 2006) (Registration No. 001-33137).
10.5	*	Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2009).
10.6	*	Second Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed on April 6, 2012).
10.7	*	Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Appendix A to the

		Company's definitive proxy statement on Schedule 14A filed on April 7, 2014).
10.8	*	Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).
10.9		Emergent BioSolutions Inc. Stock Incentive Plan (incorporated by reference to Exhibit 99 to Registration Statement on Form S-8, filed on May 30, 2018.)
10.10	#*	Form of Director Nonstatutory Stock Option Agreement.
10.11	#*	Form of Director Restricted Stock Unit Agreement.
10.12	#*	Form of Non-Qualified Stock Option Agreement.
10.13	#*	Form of Restricted Stock Unit Agreement.
10.14	#*	Form of Non-Qualified Stock Option Agreement. – Canadian Participant.
10.15	#*	Form of Restricted Stock Unit Agreement. – Canadian Participant.
10.16	#*	Form of Non-Qualified Stock Option Agreement. – UK Participant.
10.17	#*	Form of Restricted Stock Unit Agreement. – UK Participant.
10.18	#*	Form of Non-Qualified Stock Option Agreement. – Swiss Participant.
10.19	#*	Form of Restricted Stock Unit Agreement. – Swiss Participant.
10.20	#*	Form of Non-Qualified Stock Option Agreement. – Irish Participant.
10.21	#*	Form of Restricted Stock Unit Agreement. – Irish Participant.
10.22	*	Form of Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 21, 2017).
10.23	*	Form of 2018-2020 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 14, 2018).
10.24	*	Form of 2019-2021 Performace-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 12, 2019).
10.25	*	Form of Indemnity Agreement for directors and senior officers (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on January 18, 2013).
10.26	*	Director Compensation Program (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.27	*	Annual Bonus Plan for Executive Officers (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 5, 2010).
10.28	*	Amended and Restated Senior Management Severance Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 22, 2011).
10.29	*	Second Amended and Restated Senior Management Severance Plan (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on July 16, 2015).
10.30		Amended and Restated Marketing Agreement, dated as of November 5, 2008, between Emergent Biodefense Operations Lansing LLC (formerly known as Emergent Biodefense Operations Lansing Inc.) and Intergen N.V. (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on March 6, 2009).
10.31	†	Solicitation/Contract/Order for Commercial Items (the "CDC BioThrax Procurement Contract"), effective December 8, 2016, from the Centers for Disease Control and Prevention to Emergent Biodefense Operations Lansing LLC (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed on February 28, 2017).
10.32	†	Modification No. 1, effective January 27, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.33	†	Modification No. 2, effective February 23,2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.34		Modification No. 3, effective March 22, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.35	†	Modification No. 4, effective April 5, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.36	†	Modification No. 5, effective September 8, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.26 to the Company's Quarterly Report on Form 10-Q filed on November 3, 2017).
10.37	†	Modification No. 6, effective September 21, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.27 the Company's Annual Report on Form 10-K filed on February 23, 2018).
10.38	†	Modification No. 7, effective February 26, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2018).
10.39		Modification No. 8, effective March 6, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2018).
10.40	†	Modification No. 9, effective June 6, 2018, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.41	†	Modification No. 10, effective June 18, 2018, to the CDC BioThrax Procurement Contract. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.42	†	Modification No. 11, effective June 20, 2018, to the CDC BioThrax Procurement Contract. (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.43	†	Modification No. 12, effective June 21, 2018, to the CDC BioThrax Procurement Contract. (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2018).
10.44	†	Modification No. 13, effective December 6, 2018 to the CDC BioThrax Procurement (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 2, 2018).
10.45	#††	Modification No. 14, effective October 1, 2018, to the CDC BioThrax Procurement Contract
10.46	#††	Modification No. 15, effective December 7, 2018, to the CDC BioThrax Procurement Contract
10.47	#	Modification No. 16, effective December 8, 2018, to the CDC BioThrax Procurement Contract
10.48	†	Award/Contract (the "BARDA NuThrax Contract"), effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2016).
10.49	†	Modification No. 1, effective March 16, 2017, to the BARDA NuThrax Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2016) (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 5, 2017).
10.50	†	Modification No. 2, effective August 29, 2018, to the BARDA NuThrax Contract (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 2, 2018).
10.51	#††	License Agreement, dated as of December 15, 2014, by and between Opiant Pharmaceuticals, Inc. (formerly known as Lightlake Therapeutics Inc.) and Adapt Pharma Operations Limited.
10.52	#††	Amendment No. 1 to License Agreement, dated as of December 13, 2016, by and between Opiant Pharmaceuticals, Inc. and Adapt Pharma Operations Limited.
21	#	Subsidiaries of the Company.
23	#	Consent of Independent Registered Public Accounting Firm.
31.1	#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).
31.2	#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1	#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Taxonomy Calculation Linksbase Document
101.DEF		XBRL Taxonomy Definition Linksbase Document
101.LAB		XBRL Taxonomy Label Linksbase Document

101.PRE	XBRL Taxonomy Presentation Linksbase Document
#	Filed herewith
†	Confidential treatment granted by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
††	Confidential treatment requested by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
*	Management contract or compensatory plan or arrangement filed herewith in response to Item 15(a) of Form 10-K.

Attached as Exhibit 101 to this Annual Report on Form 10-K are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2018 and 2017, (ii) Consolidated Statements of Operations for the Years Ended December 31, 2018, 2017 and 2016, (iii) Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2018, 2017 and 2016 (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2018, 2017 and 2016, (v) Consolidated Statements of Changes in Stockholders' Equity for the Years ended December 31, 2018, 2017 and 2016, and (vi) Notes to Consolidated Financial Statements.

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.

EMERGENT BIOSOLUTIONS INC.

By: /s/RICHARD S. LINDAHL
Richard S. Lindahl
Executive Vice President, Chief Financial Officer and Treasurer
Date: February 21, 2019

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

Signature	Title	Date
/s/Daniel J. Abdun-Nabi Daniel J. Abdun-Nabi	Chief Executive Officer and Director (Principal Executive Officer)	February 21, 2019
/s/Richard S. Lindahl Richard S. Lindahl	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 21, 2019
/s/Fuad El-Hibri Fuad El-Hibri	Executive Chairman of the Board of Directors	February 21, 2019
/s/Zsolt Harsanyi, Ph.D. Zsolt Harsanyi, Ph.D.	Director	February 21, 2019
/s/Kathryn Zoon, Ph.D. Kathryn Zoon, Ph.D.	Director	February 21, 2019
/s/Ronald B. Richard Ronald B. Richard	Director	February 21, 2019
/s/Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Director	February 21, 2019
/s/Dr. Sue Bailey Dr. Sue Bailey	Director	February 21, 2019
/s/George Joulwan George Joulwan	Director	February 21, 2019
/s/Jerome Hauer, Ph.D. Jerome Hauer, Ph.D.	Director	February 21, 2019

Emergent BioSolutions Inc.
Form of Director Nonstatutory Stock Option Agreement

1. Grant of Option.

This agreement evidences the grant by Emergent BioSolutions Inc., a Delaware corporation (the "***Company***"), on _____ (the "***Grant Date***") to _____, a non-employee director of the Company (the "***Participant***"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's Stock Incentive Plan (the "***Plan***"), a total of _____ shares (the "***Shares***") of common stock, $0.001 par value per share, of the Company ("***Common Stock***") at $_____ per Share. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on _____ (the "***Final Exercise Date***").

It is intended that the option evidenced by this agreement shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "***Code***"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

This option will become exercisable ("***vest***") one-third per year over three years on the day immediately prior to the applicable anniversary of the date of grant (or if earlier, on the date which is one business day prior to date of the Company's next annual meeting), in each case provided that the individual is serving on the Board, or is an employee of or consultant to the Company, on such date; provided that no additional vesting shall take place after the Participant ceases to provide services to the Company; and, further provided, that the Board may provide for accelerated vesting in the case of death or disability.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing in the form attached hereto as Exhibit A or in another form as prescribed by the Company, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, and payment in full in the manner provided as follows:

The form of consideration acceptable for exercise of any option (but not for the payment of any applicable withholding or other taxes or any other financial obligation of the option holder) shall be:

1. Cash or by check payable to the order of the Corporation; or
2. by delivery (i) of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;
3. by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the option holder valued at fair market value on the date on which the shares of Common Stock are delivered to the Corporation (which fair market value shall be the closing price of the Common Stock on the New York Stock Exchange (or such other principal exchange on which the Common Stock is then listed for trading) on the date immediately preceding the delivery to the Corporation of the Common Stock) provided: (i) such payment is then permitted by applicable law; (ii) such Common Stock was owned by the option holder for a period of not less than six months prior to delivery to the Corporation; and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements on the date of delivery; or
4. Any combination of the foregoing

The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee, officer or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "***Eligible Participant***").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate 90 days after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the

Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause, the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship.

4. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

5. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, shall be exercisable only by the Participant; provided, however, that the gratuitous transfer of this Option by the Participant to or for the benefit of any immediate family member, domestic partner, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if, with respect to such proposed transferee, the Company would be eligible to use a Registration Statement on Form S-8 for the registration of the sale of the Common Stock subject to such Option under the Securities Act of 1933, as amended; provided, further, that the Company shall not be required to recognize any such transfer until such time as the Participant and such authorized transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Option; and, provided, further, that no option intended to be an incentive stock option shall be transferable unless the Board of Directors shall otherwise permit.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this option.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Agreement Date.

EMERGENT BIOSOLUTIONS INC.

_____
Name:
Title:

PARTICIPANT

_____
Name:

EMERGENT BIOSOLUTIONS INC.
Form of Director Restricted Stock Unit Agreement

This Restricted Stock Unit Agreement is made as of the Agreement Date between Emergent BioSolutions Inc. (the "Company"), a Delaware corporation, and the Participant.

I. Agreement Date

Date:	

II. Participant Information

Participant:	

III. Grant Information

Grant Date:	
Number of RSUs:	

IV. Vesting

These restricted stock units ("RSUs") shall vest one-third per year over three years on the day immediately prior to the applicable anniversary of the date of grant (or if earlier, on the date which is one business day prior to date of the Company's next annual meeting), in each case provided that the individual is serving on the Board, or is an employee of or consultant to, the Company on such date, provided that no additional vesting shall take place after the Participant ceases to provide services to the Company and further provided that the Board may provide for accelerated vesting in the case of death or disability.

This Agreement includes this cover page and the following Exhibit, which is expressly incorporated by reference in its entirety herein:

Exhibit A – General Terms and Conditions

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Agreement Date.

EMERGENT BIOSOLUTIONS INC.

_____
Name:
Title:

PARTICIPANT

_____
Name:

EMERGENT BIOSOLUTIONS INC.

Form of Director Restricted Stock Unit Award Agreement

Exhibit A – General Terms and Conditions

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Grant of RSUs. In consideration of services rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth in this Agreement and in the Company's Stock Incentive Plan (the "Plan"), an award of Restricted Stock Units (the "RSUs"), representing the number of RSUs set forth on the cover page of this Agreement. The RSUs entitle the Participant to receive, upon and subject to the vesting of the RSUs (as described in Section 2 below), one share of common stock, $0.001 par value per share, of the Company (the "Common Stock") for each RSU that vests. The shares of Common Stock that are issuable upon vesting of the RSUs are referred to in this Agreement as the "Shares".

2. Vesting of RSUs and Issuance of Shares.

(a) General. Subject to the other provisions of this Section 2, the RSUs shall vest in accordance with the vesting table set forth on the cover page of this Agreement (the "Vesting Table"). Any fractional RSU resulting from the application of the percentages in the Vesting Table shall be rounded to the nearest whole number of RSUs. Subject to Section 4, as soon as administratively practicable after each vesting date shown in the Vesting Table (the "Vesting Dates"), the Company will issue to the Participant, in certificated or uncertificated form, such number of Shares as is equal to the number of RSUs that vested on such Vesting Date. In no event shall the Shares be issued to the Participant later than 75 days after the Vesting Date.

(b) Service Termination. Except as set forth in Section 2(c) below, upon the termination of the Participant's service with the Company on the Board of Directors of the Company, or as an employee of or consultant to the Company, for any reason, all unvested RSUs shall be automatically forfeited as of such service termination. For purposes of this Agreement, service with the Company shall include service with a parent or subsidiary of the Company, or any successor to the Company.

(c) Change in Control Event. Upon a Change in Control Event (as defined in the Plan), the RSUs shall be treated in the manner provided in Section 9(b)(iii)(B) of the Plan.

3. Dividends. At the time of the issuance of Shares to the Participant pursuant to Section 2, the Company shall also pay to the Participant an amount of cash equal to the aggregate amount of all dividends paid by the Company, between the Grant Date and the issuance of such Shares, with respect to the number of Shares so issued to the Participant.

4. Withholding Taxes. The Participant must satisfy all applicable federal, state, and local and other income and employment tax withholding obligations associated with the grant, vesting and settlement of the RSUs before the Company will issue any Shares hereunder following a Vesting Date. The withholding obligation may be satisfied by any method permitted under the Plan.

5. Restrictions on Transfer. Neither the RSUs, nor any interest therein (including the right to receive dividend payments in accordance with Section 3), may be transferred by the Participant except to the extent specifically permitted in Section 10(a) of the Plan.

6. Provisions of the Plan. This Agreement is subject to the provisions of the Plan. The Participant acknowledges receipt of the Plan, along with the Prospectus relating to the Plan.

7. Section 409A. This Agreement is intended to comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A") and shall be interpreted and construed consistently therewith. In no event shall either the Participant or the Company have the right to accelerate or defer delivery of the Shares to a date or event other than as set forth in this Agreement except to the extent specifically permitted or required by Section 409A. In the event that the Participant is a "specified employee" within the meaning of Section 409A and the Shares are to be delivered pursuant to this Agreement in connection with the termination of the Participant's employment, the delivery of the Shares and any dividends payable under Section 3 in connection with such delivery shall be delayed until the date that is six months and one day following the date of the Participant's termination of employment if required to avoid the imposition of additional taxes under Section 409A. Solely for purposes of determining when the Shares (and any dividends payable under Section 3) may be delivered in connection with the Participant's termination of employment, such termination of employment must constitute a "separation from service" within the meaning of Section 409A.

8. Miscellaneous.

(a) No Rights to Service. The Participant acknowledges and agrees that the grant of the RSUs and their vesting pursuant to Section 2 do not constitute an express or implied promise of continued service with the Company for the vesting period, or for any period.

(b) Entire Agreement. This Agreement and the Plan constitute the entire agreement between the parties, and supersede all prior agreements and understandings, relating to the subject matter of this Agreement; provided that any separate employment, consulting or severance plan or agreement between the Company and the Participant that includes terms relating to the acceleration of vesting of equity awards shall not be superseded by this Agreement.

(c) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflict of law principles.

(d) Interpretation. The interpretation and construction of any terms or conditions of the Plan or this Agreement by the Compensation Committee shall be final and conclusive.

EXHIBIT 10.12

Emergent BioSolutions Inc.
Non-Qualified Stock Option Award Agreement

1. Grant of Option.

This evidences the grant by Emergent BioSolutions Inc., a Delaware corporation (the "*Company*"), to an employee of the Company (the "*Participant*"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's Stock Incentive Plan (the "*Plan*"), that number of shares (the "*Shares*") of common stock, with a $0.001 par value per share, of the Company ("Common Stock") set forth under the summary of the grant in your account in the Company's third-party electronic stock administrative platform (the "Grant Summary") at the *Grant Price* identified on the Grant Summary. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the *Expiration Date* identified on the Grant Summary.

This option shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "*Code*"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

This non-qualified stock option shall vest in the aggregate in three equal annual installments on the day immediately prior to each anniversary of the grant date. Specifically, this option shall vest in accordance with the future vesting schedule as viewed under your account in the Company's third-party electronic stock administrative platform.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Expiration Date or the termination of this option under Section 3 hereof or the Plan.

3. Form of Exercise. Each election to exercise this option shall be in accordance with the Company's policies and procedures.

The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(a) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the grant date, an employee, officer or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "*Eligible Participant*").

(b) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (c) and (d) below, the right to exercise this option shall terminate 90 days after such cessation (but in no event after the Expiration Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Expiration Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(c) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Expiration Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (d) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Expiration Date.

(d) Termination for Cause. If, prior to the Expiration Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause (as defined in the Plan), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship.

4. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

5. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, shall be exercisable only by the Participant; provided, however, that the gratuitous transfer of this Option by the Participant to or for the benefit of any immediate family member, domestic partner, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if, with respect to such proposed transferee, the Company would be eligible to use a Registration Statement on Form S-8 for the registration of the sale of the Common Stock subject to such Option under the Securities Act of 1933, as amended; provided, further, that the Company shall not be required to recognize any such transfer until such time as the Participant and such authorized transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Option; and, provided, further, that no option intended to be an incentive stock option shall be transferable unless the Board of Directors shall otherwise permit.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this option.

Emergent BioSolutions Inc.
Form of Restricted Stock Unit Award Agreement

1. Grant of RSUs. In consideration of services rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth herein and in the Company's Stock Incentive Plan (the "Plan"), an award of Restricted Stock Units (the "RSUs"), representing the number of RSUs set forth under your account in the Company's third-party electronic stock administrative platform. The RSUs entitle the Participant to receive, upon and subject to the vesting of the RSUs (as described in Section 2 below), one share of common stock, $0.001 par value per share, of the Company (the "Common Stock") for each RSU that vests. The shares of Common Stock that are issuable upon vesting of the RSUs are referred to herein as the "Shares."

2. Vesting of RSUs and Issuance of Shares.

(a) General. Subject to the other provisions of this Section 2, the RSUs shall vest one-third per year over three years on the day immediately prior to the applicable anniversary of the grant date, in accordance with the future vesting schedule (the "Vesting Schedule") set forth under your account in the Company's third-party electronic stock administrative platform. Subject to Section 4, as soon as administratively practicable after each vesting date shown in the Vesting Schedule (each a "Vesting Date"), the Company will issue to the Participant, in certificated or uncertificated form, such number of Shares as is equal to the number of RSUs that vested on such Vesting Date. In no event shall the Shares be issued to the Participant later than 75 days after the Vesting Date.

(b) Service Termination. Except as set forth in Section 2(c) below, upon the cessation of the Participant's service with the Company as an employee, consultant or director of the Company for any reason, all unvested RSUs shall be automatically forfeited as of such cessation of service. For purposes of this RSU award, service with the Company shall include service as an employee or director of, or consultant to, the Company or to a parent or subsidiary of the Company, or any successor to the Company.

(c) Change in Control Event. Upon a Change in Control Event (as defined in the Plan), the RSUs shall be treated in the manner provided in Section 9(b)(iii)(B) of the Plan.

3. Dividends. At the time of the issuance of Shares to the Participant pursuant to Section 2, the Company shall also pay to the Participant an amount of cash equal to the aggregate amount of all dividends paid by the Company, between the grant date and the issuance of such Shares, with respect to the number of Shares so issued to the Participant.

4. Withholding Taxes. The Participant must satisfy all applicable federal, state, and local and other income and employment tax withholding obligations associated with the grant, vesting and settlement of the RSUs before the Company will issue any Shares hereunder following a Vesting Date. The withholding obligation may be satisfied by any method permitted under the Plan.

5. Restrictions on Transfer. Neither the RSUs, nor any interest therein (including the right to receive dividend payments in accordance with Section 3), may be transferred by the Participant except to the extent specifically permitted in Section 10(a) of the Plan.

6. Provisions of the Plan. This RSU award is subject to the provisions of the Plan. The Participant acknowledges receipt of the Plan, along with the Prospectus relating to the Plan.

7. Section 409A. This RSU award is intended to comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A") and shall be interpreted and construed consistently therewith. In no event shall either the Participant or the Company have the right to accelerate or defer delivery of the Shares to a date or event other than as set forth herein except to the extent specifically permitted or required by Section 409A. In the event that the Participant is a "specified employee" within the meaning of Section 409A and the Shares are to be delivered in connection with the termination of the Participant's employment, the delivery of the Shares and any dividends payable under Section 3 in connection with such delivery shall be delayed until the date that is six months and one day following the date of the Participant's termination of employment if required to avoid the imposition of additional taxes under Section 409A. Solely for purposes of determining when the Shares (and any dividends payable under Section 3) may be delivered in connection with the Participant's termination of employment, such termination of employment must constitute a "separation from service" within the meaning of Section 409A.

8. Miscellaneous.

(a) No Rights to Service. The Participant acknowledges and agrees that the grant of the RSUs and their vesting pursuant to Section 2 do not constitute an express or implied promise of continued employment or service with the Company for the vesting period, or for any period.

(b) Entire Agreement. These terms and the Plan constitute the entire agreement between the parties, and supersede all prior agreements and understandings, relating to the subject matter of this RSU award; provided that any separate employment, consulting, or severance plan or agreement between the Company and the Participant that includes terms relating to the acceleration of vesting of equity awards shall not be superseded by these terms.

(c) Governing Law. This RSU award shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflict of law principles.

(d) Interpretation. The interpretation and construction of any terms or conditions of the Plan or this RSU award by the Compensation Committee shall be final and conclusive.

EXHIBIT 10.14

Emergent BioSolutions Inc.
Non-Qualified Stock Option Award Agreement – Canadian Participant

1. Grant of Option.

This evidences the grant by Emergent BioSolutions Inc., a Delaware corporation (the "*Company*"), to an employee of the Company (the "*Participant*"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's Stock Incentive Plan (the "*Plan*"), that number of shares (the "*Shares*") of common stock, with a $0.001 par value per share, of the Company ("Common Stock") set forth under the summary of the grant in your account in the Company's third-party electronic stock administrative platform (the "Grant Summary") at the *Grant Price* identified on the Grant Summary. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the *Expiration Date* identified on the Grant Summary.

This option shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "*Code*"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

The grant of options under the Plan is made at the discretion of the Company and the Plan may be suspended or terminated by the Company at any time.

2. Vesting Schedule.

This non-qualified stock option shall vest in the aggregate in three equal annual installments on the day immediately prior to each anniversary of the grant date. Specifically, this option shall vest in accordance with the future vesting schedule indicated on the detailed view of the option as viewed under your account in the Company's third-party electronic stock administrative platform.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Expiration Date or the termination of this option under Section 3 hereof or the Plan.

3. Form of Exercise.

Each election to exercise this option shall be in accordance with the Company's policies and procedures.

The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(a) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the grant date, an employee, officer or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "*Eligible Participant*").

(b) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (c) and (d) below, the right to exercise this option shall terminate 90 days after such cessation (but in no event after the Expiration Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Expiration Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(c) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Expiration Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (d) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Expiration Date.

(d) Termination for Cause. If, prior to the Expiration Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause (as defined in the Plan), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship.

4. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state, provincial or local withholding taxes, including but not limited to those under the Income Tax Act (Canada), the Canadian Pension Plan Act or any other applicable tax required by law to be withheld in respect of this option.

5. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, shall be exercisable only by the Participant; provided, however, that the gratuitous transfer of this Option by the Participant to or for the benefit of any immediate family member, domestic partner, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if, with respect to such proposed transferee, the Company would be

eligible to use a Registration Statement on Form S-8 for the registration of the sale of the Common Stock subject to such Option under the Securities Act of 1933, as amended; provided, further, that the Company shall not be required to recognize any such transfer until such time as the Participant and such authorized transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Option; and, provided, further, that no option intended to be an incentive stock option shall be transferable unless the Board of Directors shall otherwise permit.

6. Data Privacy.

The Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of his personal data by and among, as applicable, his or her employing entity or contracting party and the Company for the exclusive purpose of implementing, administering and managing his participation in the Plan. The Participant understands that the Company holds certain personal information about him, including, but not limited to, his name, home address and telephone number, work location and phone number, date of birth, hire date, details of all awards or any other entitlement to shares awarded, cancelled, exercised, vested, unvested or outstanding in the Participant's favor, for the purpose of implementing, administering and managing the Plan ("Personal Data"). The Participant understands that Personal Data may be transferred to any third parties assisting in the implementation, administration and management of the Plan (an "Administrator"), that such Administrator may be located in the Participant's country or elsewhere, and that the Administrator's country may have different data privacy laws and lower protections than the Participant's country. The Participant understands that he may request a list with the names and addresses of any potential Administrator with access to the Personal Data by contacting his local human resources representative. The Participant authorizes the Administrator to receive, possess, use, retain and transfer the Personal Data, in electronic or other form, for the purposes of implementing, administering and managing his participation in the Plan. The Participant understands that Personal Data will be held only as long as is necessary to implement, administer and manage his participation in the Plan. The Participant understands that he may, at any time, view Personal Data, request additional information about the storage and processing of Personal Data, require any necessary amendments to Personal Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing his local human resources representative. The Participant understands, however, that refusing or withdrawing his consent may affect his ability to participate in the Plan. For more information on the consequences of Participant's refusal to consent or withdrawal of consent, the Participant understands that he may contact his local human resources representative.

7. Provisions of the Plan.

This option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this option.

Emergent BioSolutions Inc.
Form of Restricted Stock Unit Award Agreement – Canadian Participant

1. Grant of RSUs.

In consideration of services rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth herein and in the Company's Stock Incentive Plan (the "Plan"), an award of Restricted Stock Units (the "RSUs"), representing the number of RSUs set forth under your account in the Company's third-party electronic stock administrative platform. The RSUs entitle the Participant to receive, upon and subject to the vesting of the RSUs (as described in Section 2 below), one share of common stock, $0.001 par value per share, of the Company (the "Common Stock") for each RSU that vests. The shares of Common Stock that are issuable upon vesting of the RSUs are referred to herein as the "Shares."

The grant of RSUs under the Plan is made at the discretion of the Company and the Plan may be suspended or terminated by the Company at any time.

2. Vesting of RSUs and Issuance of Shares.

(a) General. Subject to the other provisions of this Section 2, the RSUs shall vest one-third per year over three years on the day immediately prior to the applicable anniversary of the grant date, in accordance with the future vesting schedule (the "Vesting Schedule") set forth under your account in the Company's third-party electronic stock administrative platform. Subject to Section 4, as soon as administratively practicable after each vesting date shown in the Vesting Schedule (each a "Vesting Date"), the Company will issue to the Participant, in certificated or uncertificated form, such number of Shares as is equal to the number of RSUs that vested on such Vesting Date. In no event shall the Shares be issued to the Participant later than 75 days after the Vesting Date.

(b) Service Termination. Except as set forth in Section 2(c) below, upon the cessation of the Participant's service with the Company as an employee, consultant or director of the Company for any reason, all unvested RSUs shall be automatically forfeited as of such cessation of service. For purposes of this RSU award, service with the Company shall include service as an employee or director of, or consultant to, the Company or to a parent or subsidiary of the Company, or any successor to the Company.

(c) Change in Control Event. Upon a Change in Control Event (as defined in the Plan), the RSUs shall be treated in the manner provided in Section 9(b)(iii)(B) of the Plan.

3. Dividends.

At the time of the issuance of Shares to the Participant pursuant to Section 2, the Company shall also pay to the Participant an amount of cash equal to the aggregate amount of all dividends paid by the Company, between the grant date and the issuance of such Shares, with respect to the number of Shares so issued to the Participant.

4. Withholding Taxes.

The Participant must satisfy all applicable federal, state, provincial and local withholding taxes, including but not limited to those under the Income Tax Act (Canada), the Canadian Pension Plan Act or any other applicable tax, required by law to be withheld in connection with the grant, vesting and settlement of the RSUs before the Company will issue any Shares hereunder following a Vesting Date. The withholding obligation may be satisfied by any method permitted under the Plan.

5. Restrictions on Transfer.

Neither the RSUs, nor any interest therein (including the right to receive dividend payments in accordance with Section 3), may be transferred by the Participant except to the extent specifically permitted in Section 10(a) of the Plan.

6. Data Privacy.

The Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of his personal data by and among, as applicable, his or her employing entity or contracting party and the Company for the exclusive purpose of implementing, administering and managing his participation in the Plan. The Participant understands that the Company holds certain personal information about him, including, but not limited to, his name, home address and telephone number, work location and phone number, date of birth, hire date, details of all awards or any other entitlement to shares awarded, cancelled, exercised, vested, unvested or outstanding in the Participant's favor, for the purpose of implementing, administering and managing the Plan ("Personal Data"). The Participant understands that Personal Data may be transferred to any third parties assisting in the implementation, administration and management of the Plan (an "Administrator"), that such Administrator may be located in the Participant's country or elsewhere, and that the Administrator's country may have different data privacy laws and lower protections than the Participant's country. The Participant understands that he may request a list with the names and addresses of any potential Administrator with access to the Personal Data by contacting his local human resources representative. The Participant authorizes the Administrator to receive, possess, use, retain and transfer the Personal Data, in electronic or other form, for the purposes of implementing, administering and managing his participation in the Plan. The Participant understands that Personal Data will be held only as long as is necessary to implement, administer and manage his participation in the Plan. The Participant understands that he may, at any time, view Personal Data, request additional information about the storage and processing of Personal Data, require any necessary amendments to Personal Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing his local human resources representative. The Participant understands, however, that refusing or withdrawing his consent may affect his ability to participate in the Plan. For more information on the consequences of Participant's refusal to consent or withdrawal of consent, the Participant understands that he may contact his local human resources representative.

7. Provisions of the Plan.

This RSU award is subject to the provisions of the Plan. The Participant acknowledges receipt of the Plan, along with the Prospectus relating to the Plan.

8. Section 409A.

This RSU award is intended to comply with or be exempt from Section 409A of the U.S. Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A") and shall be interpreted and construed consistently therewith. In no event shall either the Participant or the Company have the right to accelerate or defer delivery of the Shares to a date or event other than as set forth herein except to the extent specifically permitted or required by Section 409A. In the event that the Participant is a "specified employee" within the meaning of Section 409A and the Shares are to be delivered in connection with the termination of the Participant's employment, the delivery of the Shares and any dividends payable under Section 3 in connection with such delivery shall be delayed until the date that is six months and one day following the date of the Participant's termination of employment if required to avoid the imposition of additional taxes under Section 409A. Solely for purposes of determining when the Shares (and any dividends payable under Section 3) may be delivered in connection with the Participant's termination of employment, such termination of employment must constitute a "separation from service" within the meaning of Section 409A.

9. Miscellaneous.

(a) No Rights to Service. The Participant acknowledges and agrees that the grant of the RSUs and their vesting pursuant to Section 2 do not constitute an express or implied promise of continued employment or service with the Company for the vesting period, or for any period.

(b) Entire Agreement. These terms and the Plan constitute the entire agreement between the parties, and supersede all prior agreements and understandings, relating to the subject matter of this RSU award; provided that any separate employment, consulting or severance plan or agreement between the Company and the Participant that includes terms relating to the acceleration of vesting of equity awards shall not be superseded by these terms.

(c) Governing Law. This RSU award shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflict of law principles.

(d) Interpretation. The interpretation and construction of any terms or conditions of the Plan or this RSU award by the Compensation Committee shall be final and conclusive.

Emergent BioSolutions Inc.

Non-Qualified UK Stock Option Award Agreement – UK Participant

1. Grant of Option.

This UK Stock Option Award Agreement evidences the grant by Emergent BioSolutions Inc., a Delaware corporation (the "Company"), to a UK employee of the Company (the "Participant"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's Stock Incentive Plan (the "Plan"), that number of shares (the "Shares") of common stock, with a $0.001 par value per share, of the Company ("Common Stock") set forth under the summary of the grant in your account in the Company's third-party electronic stock administrative platform (the "Grant Summary") at the Grant Price identified on the Grant Summary. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Expiration Date identified on the Grant Summary.

This option shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

The grant of options under the Plan is made at the discretion of the Company and the Plan may be suspended or terminated by the Company at any time.

The Company does not give any advice or any guarantee as to how the grant, vesting or exercise of the option will be taxed and the Participant should consult an independent financial adviser in that respect.

2. Vesting Schedule.

This non-qualified stock option shall vest in the aggregate in three equal annual installments on the day immediately prior to each anniversary of the grant date. Specifically, this option shall vest in accordance with the future vesting schedule indicated on the detailed view of the option as viewed under your account in the Company's third-party electronic stock administrative platform.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Expiration Date or the termination of this option under Section 3 hereof or the Plan.

3. Form of Exercise.

Each election to exercise this option shall be in accordance with the Company's policies and procedures.

The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(a) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the grant date, an employee or director of, the Company or any other entity the employees or, directors, of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(b) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (c) and (d) below, the right to exercise this option shall terminate 90 days after such cessation (but in no event after the Expiration Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Expiration Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(c) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Expiration Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (d) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Expiration Date.

(d) Termination for Cause. If, prior to the Expiration Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause (as defined in the Plan), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship.

4. UK Tax Obligations

(a) Tax Indemnity. The Participant agrees to indemnify and keep indemnified his employing company (the "Employer") and the Company from and against any liability for or obligation to pay any Tax Liability (a "Tax Liability" being any liability for income tax, employee's National Insurance contributions and (at the discretion of the Company and where lawful) employer's National Insurance Contributions (or other similar obligations to pay tax and social security wherever in the world arising) that is attributable to: (1) the grant or any benefit derived by Participant from, the grant, vesting or exercise of the option or the Shares which are the subject of the option; (2) the transfer or issue of Shares to Participant on exercise of the option; (3) any restrictions applicable to the Shares held by the Participant ceasing to apply to those shares; or (4) the disposal of any Shares.

(b) Tax Liability. The Company will not issue any Shares on exercise of this option until the Participant has made such arrangements as the Company may require for the satisfaction of any Tax Liability that may arise in connection with exercise of this option and/or the acquisition of the Shares by the Participant. The Company shall not be required to issue, allot or transfer Shares until Participant has satisfied this obligation.

(c) Election. The Participant undertakes that upon request by the Company, he/she will (on or within 14 days acquiring the Shares) join with his Employer in electing, pursuant to Section 431(1) of the Income Tax (Earnings and Pensions) Act 2003 ("ITEPA") that, for relevant tax purposes, the market value of the Shares acquired on exercise of the option on any occasion will be calculated as if the Shares were not restricted and Sections 425 to 430 (inclusive) of ITEPA are not to apply to such Shares.

(d) The Company has the right and option, but not the obligation, to treat the Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the option as the Participant's election to satisfy all or any portion of the withholding tax by requesting the Company repurchase Shares otherwise issuable under the option on exercise limited to the number of Shares which have an aggregate fair market value on the date of repurchase necessary to pay the aggregate amount of Tax Liability.

(e) The Participant acknowledges that the Participant is ultimately liable and responsible for all taxes owed in connection with the option, regardless of any action the Company takes with respect to any tax withholding obligations that arise in connection with the option. The Company does not make any representation or undertaking regarding the treatment of any tax withholding in connection with the vesting or exercise of the option or the subsequent sale of Shares. The Company does not commit and is under no obligation to structure the option to reduce or eliminate the Participant's Tax Liability.

5. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, shall be exercisable only by the Participant; provided, however, that the gratuitous transfer of this option by the Participant to or for the benefit of any immediate family member, domestic partner, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if, with respect to such proposed transferee, the Company would be eligible to use a Registration Statement on Form S-8 for the registration of the sale of the Common Stock subject to such option under the Securities Act of 1933, as amended; provided, further, that the Company shall not be required to recognize any such transfer until such time as the Participant and such authorized transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the option; and, provided, further, that no option intended to be an incentive stock option shall be transferable unless the Board of Directors shall otherwise permit.

6. Data Protection

(a) The Participant expressly acknowledges that the Company's processing of his personal data is necessary:

i. for the performance of this UK Stock Option Award Agreement;

ii. for the legitimate interests of the Company (which includes all the interests noted in Section 6(b) (i)-(vi) below); and/or

iii. to comply with the Company's legal obligations in the UK and/or other EU member states in connection with: (a) the Participant's employment; (b) any litigation, internal or regulatory investigation; or (c) as otherwise permitted by the Data Protection Act 1998or by Regulation EU 2016/679 (the "GDPR").

(b) The Participant further acknowledges that the Company's processing of his sensitive, or special categories of, personal data (which may include information relating to health, personal characteristics, criminal offences, allegations of criminal conduct and trade union membership) is necessary:

i. to carry out its or their obligations to the Participant in the fields of employment, social security, and/or social protection;

ii. for the purposes of preventative or occupational medicine, or the assessment of working capacity;

iii. for statistical purposes and equal opportunities monitoring;

iv. to administer its pensions and benefits schemes;

v. in connection with the establishment, exercise or defence of legal claims; and/or

vi. for reasons of substantial public interest, as further described in the Company's data protection policy.

(c) The processing may include disclosure of personal data and sensitive or special categories of personal data to third parties including benefit providers, prospective purchasers or service providers and governmental authorities.

(d) A separate privacy notice has been provided to you in accordance with article 13 of the GDPR.

(e) The Participant expressly acknowledges that the Company may transfer such data outside the European Economic Area (including, in particular, to offices in the United States) for such purposes and acknowledge that such countries may not have laws which adequately safeguard such data.

7. Acknowledgement.

The Participant acknowledges that this UK Stock Option Award Agreement has not been issued and has not been approved by, an authorised person within the meaning of the Financial Services and Markets Act 2000 of the United Kingdom and is being directed at the Participant because the offer to which this UK Stock Option Award Agreement relates has been determined as having regard to the Participant's circumstances as an employee of the Company. This UK Stock Option Award Agreement is strictly confidential and is not for distribution to, and may not be acted upon by, any other person other than the person to whom it has been specifically addressed.

8. Provisions of the Plan.

This UK Stock Option Award Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this option.

Signed by [●] [Company]

_____

acting by [●]

Date:_____

I hereby agree to accept the grant of the Option on and subject to the terms and conditions set out in the Plan and this UK Stock Option Award Agreement.

_____

[●][Name] Date

EXHIBIT 10.17

Emergent BioSolutions Inc.

Form of UK Restricted Stock Unit Award Agreement – UK Participant

1. Grant of RSUs.

In consideration of services rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth herein and in the Company's Stock Incentive Plan (the "Plan"), an award of Restricted Stock Units (the "RSUs"), representing the number of RSUs set forth under your account in the Company's third-party electronic stock administrative platform. The RSUs entitle the Participant to receive, upon and subject to the vesting of the RSUs (as described in Section 2 below), one share of common stock, $0.001 par value per share, of the Company (the "Common Stock") for each RSU that vests. The shares of Common Stock that are issuable upon vesting of the RSUs are referred to herein as the "Shares."

The grant of RSUs under the Plan is made at the discretion of the Company and the Plan may be suspended or terminated by the Company at any time.

The Company does not give any advice or any guarantee as to how the grant or vesting of the RSUs will be taxed and the Participant should consult an independent financial adviser in that respect.

2. Vesting of RSUs and Issuance of Shares.

(a) General. Subject to the other provisions of this Section 2, the RSUs shall vest one-third per year over three years on the day immediately prior to the applicable anniversary of the grant date, in accordance with the future vesting schedule (the "Vesting Schedule") set forth under your account in the Company's third-party electronic stock administrative platform. Subject to Section 4, as soon as administratively practicable after each vesting date shown in the Vesting Schedule (each a "Vesting Date"), the Company will issue to the Participant, in certificated or uncertificated form, such number of Shares as is equal to the number of RSUs that vested on such Vesting Date. In no event shall the Shares be issued to the Participant later than 75 days after the Vesting Date.

(b) Termination of Employment. Except as set forth in Section 2(c) below, upon the cessation of the Participant's employment with the Company for any reason, all unvested RSUs shall be automatically forfeited as of such cessation of employment. For purposes of this UK RSU Award Agreement, employment with the Company shall include employment as an employee or director of the Company or to a parent or subsidiary of the Company, or any successor to the Company.

(c) Change in Control Event. Upon a Change in Control Event (as defined in the Plan), the RSUs shall be treated in the manner provided in Section 9(b)(iii)(B) of the Plan.

3. Dividends.

At the time of the issuance of Shares to the Participant pursuant to Section 2, the Company shall also pay to the Participant an amount of cash equal to the aggregate amount of all dividends paid by the Company, between the grant date and the issuance of such Shares, with respect to the number of Shares so issued to the Participant.

4. UK Tax Obligations.

(a) Tax Indemnity. The Participant agrees to indemnify and keep indemnified his employing company (the "Employer") and the Company from and against any liability for or obligation to pay any Tax Liability (a "Tax Liability" being any liability for income tax, employee's National Insurance contributions and (at the discretion of the Company and where lawful) employer's National Insurance Contributions (or other similar obligations to pay tax and social security wherever in the world arising) that is attributable to: (1) the grant or any benefit derived by Participant from, the RSUs or the Shares which are the subject of the RSUs; (2) the transfer or issue of Shares to Participant on vesting of the RSUs; (3) any restrictions applicable to the Shares held by the Participant ceasing to apply to those shares; or (4) the disposal of any Shares.

(b) Tax Liability. The Company will not issue any Shares on vesting until the Participant has made such arrangements as the Company may require for the satisfaction of any Tax Liability that may arise in connection with the vesting of the RSUs and/or the acquisition of the Shares by the Participant. The Company shall not be required to issue, allot or transfer Shares until Participant has satisfied this obligation.

(c) Election. The Participant undertakes that upon request by the Company, he/she will (on or within 14 days acquiring the Shares) join with his Employer in electing, pursuant to Section 431(1) of the Income Tax (Earnings and Pensions) Act 2003 ("ITEPA") that, for relevant tax purposes, the market value of the Shares acquired on vesting of the RSUs on any occasion will be calculated as if the Shares were not restricted and Sections 425 to 430 (inclusive) of ITEPA are not to apply to such Shares.

(d) The Company has the right and option, but not the obligation, to treat the Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs as the Participant's election to satisfy all or any portion of the withholding tax by requesting the Company repurchase Shares otherwise issuable under the Award limited to the number of Shares which have an aggregate fair market value on the date of repurchase necessary to pay the aggregate amount of Tax Liability.

(e) The Participant acknowledges that the Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company takes with respect to any tax withholding obligations that arise in connection with the RSUs. The Company does not make any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding or vesting of the RSUs or the subsequent sale of Shares. The Company does not commit and is under no obligation to structure the Award to reduce or eliminate the Participant's Tax Liability.

5. Restrictions on Transfer.

Neither the RSUs, nor any interest therein (including the right to receive dividend payments in accordance with Section 3), may be transferred by the Participant except to the extent specifically permitted in Section 10(a) of the Plan.

6. Data Protection.

(a) The Participant expressly acknowledges that the Company's processing of his personal data is necessary:

i. for the performance of this UK RSU Award Agreement;

ii. for the legitimate interests of the Company (which includes all the interests noted in Section 6(b) (i)-(vi) below); and/or

iii. to comply with the Company's legal obligations in the UK and/or other EU member states in connection with: (a) the Participant's employment; (b) any litigation, internal or regulatory investigation; or (c) as otherwise permitted by the Data Protection Act 1998 or by Regulation EU 2016/679 (the "GDPR").

(b) The Participant further acknowledges that the Company's processing of his sensitive, or special categories of, personal data (which may include information relating to health, personal characteristics, criminal offences, allegations of criminal conduct and trade union membership) is necessary:

i. to carry out its or their obligations to the Participant in the fields of employment, social security, and/or social protection;

ii. for the purposes of preventative or occupational medicine, or the assessment of working capacity;

iii. for statistical purposes and equal opportunities monitoring;

iv. to administer its pensions and benefits schemes;

v. in connection with the establishment, exercise or defence of legal claims; and/or

vi. for reasons of substantial public interest, as further described in the Company's data protection policy.

(c) The processing may include disclosure of personal data and sensitive or special categories of personal data to third parties including benefit providers, prospective purchasers or service providers and governmental authorities.

(d) A separate privacy notice has been provided in accordance with article 13 of the GDPR.

(e) The Participant expressly acknowledges that the Company may transfer such data outside the European Economic Area (including, in particular, to offices in the United States) for such purposes and acknowledge that such countries may not have laws which adequately safeguard such data.

7. Provisions of the Plan.

This UK RSU Award Agreement is subject to the provisions of the Plan. The Participant acknowledges receipt of the Plan, along with the Prospectus relating to the Plan.

8. Section 409A.

This UK RSU Award Agreement is intended to comply with or be exempt from Section 409A of the U.S. Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A") and shall be interpreted and construed consistently therewith. In no event shall either the Participant or the Company have the right to accelerate or defer delivery of the Shares to a date or event other than as set forth herein except to the extent specifically permitted or required by Section 409A. In the event that the Participant is a "specified employee" within the meaning of Section 409A and the Shares are to be delivered in connection with the termination of the Participant's employment, the delivery of the Shares and any dividends payable under Section 3 in connection with such delivery shall be delayed until the date that is six months and one day following the date of the Participant's termination of employment if required to avoid the imposition of additional taxes under Section 409A. Solely for purposes of determining when the Shares (and any dividends payable under Section 3) may be delivered in connection with the Participant's termination of employment, such termination of employment must constitute a "separation from service" within the meaning of Section 409A.

9. Miscellaneous.

(a) No Rights to Service. The Participant acknowledges and agrees that the grant of the RSUs and their vesting pursuant to Section 2 do not constitute an express or implied promise of continued employment or service with the Company for the vesting period, or for any period.

(b) Entire Agreement. These terms and the Plan constitute the entire agreement between the parties, and supersede all prior agreements and understandings, relating to the subject matter of this UK RSU Award Agreement; provided that any separate employment, consulting or severance plan or agreement between the Company and the Participant that includes terms relating to the acceleration of vesting of equity awards shall not be superseded by these terms.

(c) Acknowledgement. The Participant acknowledges that this UK RSU Award Agreement has not been issued and has not been approved by, an authorised person within the meaning of the Financial Services and Markets Act 2000 of the United Kingdom and is being directed at the Participant because the offer to which this UK RSU Award Agreement relates has been determined as having regard to the Participant's circumstances as an

employee of the Company. This UK RSU Award Agreement is strictly confidential and is not for distribution to, and may not be acted upon by, any other person other than the person to whom it has been specifically addressed.

(d) Governing Law. This UK RSU Award Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflict of law principles.

(e) Interpretation. The interpretation and construction of any terms or conditions of the Plan or this UK RSU Award Agreement by the Compensation Committee shall be final and conclusive.

Signed by [●] [Company]

_____

acting by [●]

Date: _____

I hereby agree to accept the grant of the RSUs on and subject to the terms and conditions set out in the Plan and this UK RSU Award Agreement.

_____ _____

[●][*Name*] Date

EXHIBIT 10.18

Emergent BioSolutions Inc.

Non-Qualified Stock Option Award Agreement – Swiss Participant

1. Grant of Option.

This evidences the grant by Emergent BioSolutions Inc., a Delaware corporation (the "*Company*"), to an employee of the Company (the "*Participant*"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's Stock Incentive Plan (the "*Plan*"), that number of shares (the "*Shares*") of common stock, with a $0.001 par value per share, of the Company ("Common Stock") set forth under the summary of grant in your account in the Company's third-party electronic stock administrative platform (the "Grant Summary") at the *Grant Price* identified on the Grant Summary. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the *Expiration Date* identified on the Grant Summary.

This option shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "*Code*"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

The grant of options under the Plan is made at the discretion of the Company and the Plan may be suspended or terminated by the Company at any time. The award is a discretionary grant which shall not give to the Participant the right to claim any award for the following years.

2. Vesting Schedule.

This non-qualified stock option shall vest in the aggregate in three equal annual installments on the day immediately prior to each anniversary of the grant date. Specifically, this option shall vest in accordance with the future vesting schedule indicated on the detailed view of the option as viewed under your account in the Company's third-party electronic stock administrative platform.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Expiration Date or the termination of this option under Section 3 hereof or the Plan.

3. Form of Exercise.

Each election to exercise this option shall be in accordance with the Company's policies and procedures.

The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(a) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the grant date, an employee, officer or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "*Eligible Participant*").

(b) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (c) and (d) below, the right to exercise this option shall terminate 90 days after such cessation (but in no event after the Expiration Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Expiration Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(c) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Expiration Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (d) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Expiration Date.

(d) Termination for Cause. If, prior to the Expiration Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause (as defined in the Plan), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship.

4. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state, provincial or local withholding taxes or any other applicable tax required by law to be withheld in respect of this option.

5. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, shall be exercisable only by the Participant; provided, however, that the

gratuitous transfer of this Option by the Participant to or for the benefit of any immediate family member, domestic partner, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if, with respect to such proposed transferee, the Company would be eligible to use a Registration Statement on Form S-8 for the registration of the sale of the Common Stock subject to such Option under the Securities Act of 1933, as amended; provided, further, that the Company shall not be required to recognize any such transfer until such time as the Participant and such authorized transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Option; and, provided, further, that no option intended to be an incentive stock option shall be transferable unless the Board of Directors shall otherwise permit.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this option.

EXHIBIT 10.19

Emergent BioSolutions Inc.

Form of Restricted Stock Unit Award Agreement – Swiss Participant

1. Grant of RSUs.

In consideration of services rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth herein and in the Company's Stock Incentive Plan (the "Plan"), an award of Restricted Stock Units (the "RSUs"), representing the number of RSUs set forth under your account in the Company's third-party electronic stock administrative platform. The RSUs entitle the Participant to receive, upon and subject to the vesting of the RSUs (as described in Section 2 below), one share of common stock, $0.001 par value per share, of the Company (the "Common Stock") for each RSU that vests. The shares of Common Stock that are issuable upon vesting of the RSUs are referred to herein as the "Shares."

The grant of RSUs under the Plan is made at the discretion of the Company and the Plan may be suspended or terminated by the Company at any time. The award is a discretionary grant which shall not give to the Participant the right to claim any award for the following years.

2. Vesting of RSUs and Issuance of Shares.

(a) General. Subject to the other provisions of this Section 2, the RSUs shall vest one-third per year over three years on the day immediately prior to the applicable anniversary of the grant date, in accordance with the future vesting schedule (the "Vesting Schedule") set forth under your account in the Company's third-party electronic stock administrative platform. Subject to Section 4, as soon as administratively practicable after each vesting date shown in the Vesting Schedule (each a "Vesting Date"), the Company will issue to the Participant, in certificated or uncertificated form, such number of Shares as is equal to the number of RSUs that vested on such Vesting Date. In no event shall the Shares be issued to the Participant later than 75 days after the Vesting Date.

(b) Service Termination. Except as set forth in Section 2(c) below, upon the cessation of the Participant's service with the Company as an employee, consultant or director of the Company for any reason, all unvested RSUs shall be automatically forfeited as of such cessation of service. For purposes of this RSU award, service with the Company shall include service as an employee or director of, or consultant to, the Company or to a parent or subsidiary of the Company, or any successor to the Company.

(c) Change in Control Event. Upon a Change in Control Event (as defined in the Plan), the RSUs shall be treated in the manner provided in Section 9(b)(iii)(B) of the Plan.

3. Dividends.

At the time of the issuance of Shares to the Participant pursuant to Section 2, the Company shall also pay to the Participant an amount of cash equal to the aggregate amount of all dividends paid by the Company, between the grant date and the issuance of such Shares, with respect to the number of Shares so issued to the Participant.

4. Withholding Taxes.

The Participant must satisfy all applicable federal, state, provincial and local withholding taxes or any other applicable tax, required by law to be withheld in connection with the grant, vesting and settlement of the RSUs before the Company will issue any Shares hereunder following a Vesting Date. The withholding obligation may be satisfied by any method permitted under the Plan.

5. Restrictions on Transfer.

Neither the RSUs, nor any interest therein (including the right to receive dividend payments in accordance with Section 3), may be transferred by the Participant except to the extent specifically permitted in Section 10(a) of the Plan.

6. Provisions of the Plan.

This RSU award is subject to the provisions of the Plan. The Participant acknowledges receipt of the Plan, along with the Prospectus relating to the Plan.

7. Section 409A.

This RSU award is intended to comply with or be exempt from Section 409A of the U.S. Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A") and shall be interpreted and construed consistently therewith. In no event shall either the Participant or the Company have the right to accelerate or defer delivery of the Shares to a date or event other than as set forth herein except to the extent specifically permitted or required by Section 409A. In the event that the Participant is a "specified employee" within the meaning of Section 409A and the Shares are to be delivered in connection with the termination of the Participant's employment, the delivery of the Shares and any dividends payable under Section 3 in connection with such delivery shall be delayed until the date that is six months and one day following the date of the Participant's termination of employment if required to avoid the imposition of additional taxes under Section 409A. Solely for purposes of determining when the Shares (and any dividends payable under Section 3) may be delivered in connection with the Participant's termination of employment, such termination of employment must constitute a "separation from service" within the meaning of Section 409A.

8. Miscellaneous.

(a) No Rights to Service. The Participant acknowledges and agrees that the grant of the RSUs and their vesting pursuant to Section 2 do not constitute an express or implied promise of continued employment or service with the Company for the vesting period, or for any period.

(b) Entire Agreement. These terms and the Plan constitute the entire agreement between the parties, and supersede all prior agreements and understandings, relating to the subject matter of this RSU award; provided that any separate employment, consulting or severance plan or agreement between the Company and the Participant that includes terms relating to the acceleration of vesting of equity awards shall not be superseded by these terms.

(c) Governing Law. This RSU award shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflict of law principles.

(d) Interpretation. The interpretation and construction of any terms or conditions of the Plan or this RSU award by the Compensation Committee shall be final and conclusive.

EXHIBIT 10.20

Emergent BioSolutions Inc.

Non-Qualified Stock Option Award Agreement – Irish Participant

1. Grant of Option.

This evidences the grant by Emergent BioSolutions Inc., a Delaware corporation (the "*Company*"), to an employee of the Company (the "*Participant*"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's Stock Incentive Plan (the "*Plan*"), that number of shares (the "*Shares*") of common stock, with a $0.001 par value per share, of the Company ("Common Stock") set forth under the summary of the grant in your account in the Company's third-party electronic stock administrative platform (the "Grant Summary") at the *Grant Price* identified on the Grant Summary. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the *Expiration Date* identified on the Grant Summary.

This option shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "*Code*"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

The grant of options under the Plan is made at the discretion of the Company and the Plan may be suspended or terminated by the Company at any time.

2. Vesting Schedule.

This non-qualified stock option shall vest in the aggregate in three equal annual installments on the day immediately prior to each anniversary of the grant date. Specifically, this option shall vest in accordance with the future vesting schedule indicated on the detailed view of the option as viewed under your account in the Company's third-party electronic stock administrative platform.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Expiration Date or the termination of this option under Section 3 hereof or the Plan.

3. Form of Exercise. Each election to exercise this option shall be in accordance with the Company's policies and procedures.

The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(a) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the grant date, an employee, officer or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "*Eligible Participant*").

(b) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (c) and (d) below, the right to exercise this option shall terminate 90 days after such cessation (but in no event after the Expiration Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Expiration Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(c) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Expiration Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (d) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Expiration Date.

(d) Termination for Cause. If, prior to the Expiration Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause (as defined in the Plan), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship.

4. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company or the relevant subsidiaries, or makes provision satisfactory to the Company or the relevant subsidiaries for payment of, any relevant withholding taxes and social security required by law to be withheld in respect of this option.

5. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, shall be exercisable only by the Participant; provided, however, that the gratuitous transfer of this Option by the Participant to or for the benefit of any immediate family member, domestic partner, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if, with respect to such proposed transferee, the Company would be eligible to use a Registration Statement on Form S-8 for the registration of the sale of the Common Stock subject to such Option under the Securities Act of 1933, as amended; provided, further, that the Company shall not be required to recognize any such transfer until such time as the Participant and such authorized transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Option; and, provided, further, that no option intended to be an incentive stock option shall be transferable unless the Board of Directors shall otherwise permit.

6. No compensation for Loss

Under no circumstances on ceasing to be in employment or service of the Company or a subsidiary, will the Participant be entitled to any compensation for any loss of any right or benefit or prospective right or benefit under the Plan which the Participant might otherwise have enjoyed whether such compensation is claimed by way of damages for wrongful dismissal or other breach of contract or by way of compensation for loss of office or otherwise howsoever.

7. Data Protection

(a) The Participant expressly acknowledges that the Company's processing of his personal data is necessary:

i. for the performance of this Irish Stock Option Award Agreement;

ii. for the legitimate interests of the Company (which includes all the interests noted in Section 7(b) (i)-(vi) below); and/or

iii. to comply with the Company's legal obligations in Ireland and/or other EU member states in connection with: (a) the Participant's employment; (b) any litigation, internal or regulatory investigation; or (c) as otherwise permitted by the Data Protection Act 1998 or by Regulation EU 2016/679 (the "GDPR").

(b) The Participant further acknowledges that the Company's processing of his sensitive, or special categories of, personal data (which may include information relating to health, personal characteristics, criminal offences, allegations of criminal conduct and trade union membership) is necessary:

i. to carry out its or their obligations to the Participant in the fields of employment, social security, and/or social protection;

ii. for the purposes of preventative or occupational medicine, or the assessment of working capacity;

iii. for statistical purposes and equal opportunities monitoring;

iv. to administer its pensions and benefits schemes;

v. in connection with the establishment, exercise or defence of legal claims; and/or

vi. for reasons of substantial public interest, as further described in the Company's data protection policy.

(c) The processing may include disclosure of personal data and sensitive or special categories of personal data to third parties including benefit providers, prospective purchasers or service providers and governmental authorities.

(d) A separate privacy notice has been provided to you in accordance with article 13 of the GDPR.

(e) The Participant expressly acknowledges that the Company may transfer such data outside the European Economic Area (including, in particular, to offices in the United States) for such purposes and acknowledge that such countries may not have laws which adequately safeguard such data.

8. Provisions of the Plan.

This option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this option.

Emergent BioSolutions Inc.

Form of Restricted Stock Unit Award Agreement – Irish Participant

1. Grant of RSUs. In consideration of services rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth herein and in the Company's Stock Incentive Plan (the "Plan"), an award of Restricted Stock Units (the "RSUs"), representing the number of RSUs set forth under your account in the Company's third-party electronic stock administrative platform. The RSUs entitle the Participant to receive, upon and subject to the vesting of the RSUs (as described in Section 2 below), one share of common stock, $0.001 par value per share, of the Company (the "Common Stock") for each RSU that vests. The shares of Common Stock that are issuable upon vesting of the RSUs are referred to herein as the "Shares."

The grant of RSUs under the Plan is made at the discretion of the Company and the Plan may be suspended or terminated by the Company at any time.

2. Vesting of RSUs and Issuance of Shares.

(a) General. Subject to the other provisions of this Section 2, the RSUs shall vest one-third per year over three years on the day immediately prior to the applicable anniversary of the grant date, in accordance with the future vesting schedule (the "Vesting Schedule") set forth under your account in the Company's third-party electronic stock administrative platform. Subject to Section 4, as soon as administratively practicable after each vesting date shown in the Vesting Schedule (each a "Vesting Date"), the Company will issue to the Participant, in certificated or uncertificated form, such number of Shares as is equal to the number of RSUs that vested on such Vesting Date. In no event shall the Shares be issued to the Participant later than 75 days after the Vesting Date.

(b) Service Termination. Except as set forth in Section 2(c) below, upon the cessation of the Participant's service with the Company as an employee, consultant or director of the Company for any reason, all unvested RSUs shall be automatically forfeited as of such cessation of service, subject to applicable law. For purposes of this RSU award, service with the Company shall include service as an employee or director of, or consultant to, the Company or to a parent or subsidiary of the Company, or any successor to the Company.

(c) Change in Control Event. Upon a Change in Control Event (as defined in the Plan), the RSUs shall be treated in the manner provided in Section 9(b)(iii)(B) of the Plan.

3. Dividends. At the time of the issuance of Shares to the Participant pursuant to Section 2, the Company shall also pay to the Participant an amount of cash equal to the aggregate amount of all dividends paid by the Company, between the grant date and the issuance of such Shares, with respect to the number of Shares so issued to the Participant.

4. Withholding Taxes. The Participant must satisfy all income and employment tax and social security withholding obligations associated with the grant, vesting and settlement of the RSUs before the Company will issue any Shares hereunder following a Vesting Date. The withholding obligation may be satisfied by any method permitted under the Plan.

5. Restrictions on Transfer. Neither the RSUs, nor any interest therein (including the right to receive dividend payments in accordance with Section 3), may be transferred by the Participant except to the extent specifically permitted in Section 10(a) of the Plan.

6. Provisions of the Plan. This RSU award is subject to the provisions of the Plan. The Participant acknowledges receipt of the Plan, along with the Prospectus relating to the Plan.

7. Data Protection.

(a) The Participant expressly acknowledges that the Company's processing of his personal data is necessary:

(1) for the performance of this Irish RSU Award Agreement;

(2) for the legitimate interests of the Company (which includes all the interests noted in Section 7(b) (1)-(6) below); and/or

(3) to comply with the Company's legal obligations in Ireland and/or other EU member states in connection with: (a) the Participant's employment; (b) any litigation, internal or regulatory investigation; or (c) as otherwise permitted by the Data Protection Act 1998 or by Regulation EU 2016/679 (the "GDPR").

(b) The Participant further acknowledges that the Company's processing of his sensitive, or special categories of, personal data (which may include information relating to health, personal characteristics, criminal offences, allegations of criminal conduct and trade union membership) is necessary:

(1) to carry out its or their obligations to the Participant in the fields of employment, social security, and/or social protection;

(2) for the purposes of preventative or occupational medicine, or the assessment of working capacity;

(3) for statistical purposes and equal opportunities monitoring;

(4) to administer its pensions and benefits schemes;

(5) in connection with the establishment, exercise or defense of legal claims; and/or

(6) for reasons of substantial public interest, as further described in the Company's data protection policy.

(c) The processing may include disclosure of personal data and sensitive or special categories of personal data to third parties including benefit providers, prospective purchasers or service providers and governmental authorities.

(d) A separate privacy notice has been provided in accordance with article 13 of the GDPR.

8. (e) The Participant expressly acknowledges that the Company may transfer such data outside the European Economic Area (including, in particular, to offices in the United States) for such purposes and acknowledge that such countries may not have laws which adequately safeguard such data.

9. Section 409A. This RSU award is intended to comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A") and shall be interpreted and construed consistently therewith. In no event shall either the Participant or the Company have the right to accelerate or defer delivery of the Shares to a date or event other than as set forth herein except to the extent specifically permitted or required by Section 409A. In the event that the Participant is a "specified employee" within the meaning of Section 409A and the Shares are to be delivered in connection with the termination of the Participant's employment, the delivery of the Shares and any dividends payable under Section 3 in connection with such delivery shall be delayed until the date that is six months and one day following the date of the Participant's termination of employment if required to avoid the imposition of additional taxes under Section 409A. Solely for purposes of determining when the Shares (and any dividends payable under Section 3) may be delivered in connection with the Participant's termination of employment, such termination of employment must constitute a "separation from service" within the meaning of Section 409A.

10. Miscellaneous.

(a) No Rights to Service or Compensation for Loss. The Participant acknowledges and agrees that the grant of the RSUs and their vesting pursuant to Section 2 do not constitute an express or implied promise of continued employment or service with the Company for the vesting period, or for any period. Under no circumstances on ceasing to be in employment or service of the Company or a subsidiary, will the Participant be entitled to any compensation for any loss of any right or benefit or prospective right or benefit under the Plan which the Participant might otherwise have enjoyed whether such compensation is claimed by way of damages for wrongful dismissal or other breach of contract or by way of compensation for loss of office or otherwise howsoever.

(b) Entire Agreement. These terms and the Plan constitute the entire agreement between the parties, and supersede all prior agreements and understandings, relating to the subject matter of this RSU award; provided that any separate employment, consulting, or severance plan or agreement between the Company and the Participant that includes terms relating to the acceleration of vesting of equity awards shall not be superseded by these terms.

(c) Governing Law. This RSU award shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflict of law principles.

(d) Interpretation. The interpretation and construction of any terms or conditions of the Plan or this RSU award by the Compensation Committee shall be final and conclusive.

EXHIBIT 10.45

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE 1	OF PAGES

2. AMENDMENT/MODIFICATION NO. 0014	3. EFFECTIVE DATE 10/01/2018	4. REQUISITION/PURCHASE NO.	5. PROJECT NO. *(If applicable)*

6. ISSUED BY	2543	7. ADMINISTERED BY *(If other than Item 6)*	14531
CODE Centers for Disease Control and Prevention Office of Acquisition Services (OAS) 2920 Brandywine Rd, RM 3000 Atlanta, GA 30341-5539		CODE ASPR-BARDA 200 Independence Ave. SW Room 640-G Washington, DC 20201-	

8. NAME AND ADDRESS OF CONTRACTOR *(No., Street, county, State and ZIP Code)*	(√)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD LANSING, MI 48906-2933		9B. DATED *(SEE ITEM 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2017-92634
CODE 026489018 FACILITY CODE		10B. DATED *(SEE ITEM 13)* 12/08/2016

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ___ is extended, ___ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning ____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or
(c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
N/A

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(√)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER *(Specify type of modification and authority)* Unilateral FAR 42.202, Assignment of Contract Administration

E. IMPORTANT: Contractor is not, is required to sign this document and return copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
See Page 2
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME OF CONTRACTING OFFICER Lauren Peel	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY /s/ Lauren Peel *(Signature of Contracting Officer)*	16C. DATE SIGNED 10/1/18

Pursuant to FAR 42.202, Assignment of Contract Administration, the above referenced task order is modified as follows:

1. Change the contract administration office --

FROM:

Centers for Disease Control and Prevention (CDC)

Office of Acquisition Services (OAS)

2920 Brandywine Road

Atlanta, GA 30341-5539

TO:

ASPR-BARDA

200 Independence Ave. SW

Room 640-G

Washington DC 20201

2. Change the paying office – For goods/services delivered or provided by 9/30/2018, the paying office has not changed and invoices shall be sent to the Centers for Disease Control and Prevention for those delivered items. For goods/services delivered or provided on or after 10/1/2018, see paying office change below:

FROM:

Centers for Disease Control and Prevention

Financial Management Office (FMO)

PO Box 15580

Atlanta, GA 30333-0080

TO:

PSC/FMS

psc_invoices@psc.hhs.gov

3. Change the invoice instructions – For goods/services delivered or provided by 9/30/2018, the invoice instructions have not changed and the contractor shall follow the current Centers for Disease Control and Prevention instructions for those delivered items. For goods/services delivered on or after 10/1/2018, see invoice instructions change below:

TO:

INVOICES - COMMERCIAL

(a) Invoice Submission.

(1) The Contractor shall submit invoices once per month.

(2) A proper invoice, with all required back-up documentation shall be sent electronically, via email, to the COR mailbox:

(i) Contracting Officer's Representative (COR)

(3) A proper invoice, not including non-invoice related documents (i.e. deliverables, reports, balance statements) shall be sent electronically, via email, to:

(i) Contract Specialist via mailbox: [**]

(ii) Financial Management Service (FMS) via mailbox: psc_invoices@psc.hhs.gov

(4) The subject line of your email invoice submission shall contain the contract number, order number (if applicable), and the number of invoices. The Contractor shall send one email per contract per month. The email may have multiple invoices for the contract. Invoices must be in the following formats: PDF, TIFF, or Word. No Excel formats will be accepted. The electronic file cannot contain multiple invoices; example, 10 invoices requires 10 separate files (PDF or TIFF or Word).

(5) Invoices shall be submitted in accordance with the contract terms, i.e. payment schedule, progress payments, partial payments, deliverables, etc.

(6) All calls concerning contract payment shall be directed to the COR.

(7) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR Part 1315.

(b) Invoice Elements.

(1) In accordance with FAR 52.212-4, Contract Terms and Conditions-Commercial Items, the Contractor shall submit an electronic invoice to the email addresses designated in the contract to receive invoices. A proper invoice must include the following items:

(i) Name and address of the Contractor;

(ii) Invoice date and number;

(iii) Contract number, contract line item number and, if applicable, the order number;

(iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;

(vi) Terms of any discount for prompt payment offered;

(vii) Name and address of official to whom payment is to be sent;

(viii) Name, title, and phone number of person to notify in event of defective invoice; and

(ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.

(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice.

(B) In accordance with the requirements of the Debt Collection Improvement Act of 1996, all payments under this order will be made by electronic funds transfer (EFT). The Contractor shall provide financial institution information to the Finance Office designated above in accordance with FAR 52.232-33 Payment by Electronic Funds Transfer - System for A ward Management.

(2) Additionally, the Program Support Center (PSC) requires:

(i) the invoice to break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract

(ii) the invoice to include the Dun & Bradstreet Number (DUNS) of the Contractor

4. Change the Contracting Officer –

TO:

[**]

Email: [**]

Phone:[**]

5. All other items and terms and conditions remain unchanged.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	Biothrax/AVA Delivery Address: TBD Delivery Dates: Through [**] Fund partial order: [**] doses ($[**])	[**] Doses	$ [**]	$ [**]
1001	Biothrax/AVA	[**] Doses	$ [**]	$ [**]
1002	COR Change	[**]	$ [**]	$ [**]
1003	Biothrax/AVA [**].	[**] Doses	$ [**]	$ [**]
1004	Payment Instructions Update Modification request Payment Instructions in Notice of Assignment for Contract 200-2017-92634. ABA No:[**];Bank Name: [**]; Account#: [**]; Account Name: Emergent Biosolutions Inc.	[**]	$ [**]	$ [**]
1005	Biothrax/AVA	[**]Doses	$ [**]	$ [**]
1006	Biothrax/AVA	[**]	$ [**]	$ [**]
2001	Biothrax/AVA	[**]	$ [**]	$ [**]
2002	Biothrax/AVA [**]. Please see attached documents.	[**] Doses	$ [**]	$ [**]
2003	Biothrax/AVA [**]. Please see attached documents.	[**] Doses	$ [**]	$ [**]
2004	Biothrax/AVA	[**] Doses	$ [**]	$ [**]
2005	Biothrax/AVA	[**]	$ [**]	$ [**]
2006	Biothrax/AVA	[**] Doses	$ [**]	$ [**]

Option 2 Option 1 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0002	Biothrax/AVA [**]	[**] Doses	$ [**]	$ [**]

Option 3 Option 2 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0003	Biothrax/AVA Delivery Address: TBD Delivery Dates: Through [**]	[**]Doses	$ [**]	$ [**]

Option 4 Option 3 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0004	Biothrax/AVA Delivery Address: TBD Delivery Dates: Through [**]	[**]Doses	$ [**]	$ [**]

Option 5 Option 4 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0005	Biothrax/AVA Delivery Address: TBD Delivery Dates: Through [**]	[**]Doses	$ [**]	$ [**]

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 | 2

2. AMENDMENT/MODIFICATION NO. 0015	3. EFFECTIVE DATE 12/07/2018	4. REQUISITION/PURCHASE REQ NO. See Schedule	5. PROJECT NO. *(If applicable)*

6. ISSUED BY CODE ASPR-BARDA	ASPR-BARDA	7. ADMINISTERED BY *(If other than Item 6)* CODE	ASPR-BARDA02
200 Independence Ave., S.W. Room 640-G Washington DC 20201		US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*	(x)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 330303 Attn: DIANA EMERGENT BIODEFENSE OPERATIONS LANS 3500 N MARTIN LUTHER KING JR BLVD LANSING MI 489062933		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSD200201792634C
		10B. DATED *(SEE ITEM 13)* 12/08/2016
CODE 330303	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or
(c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

Net Increase:$[**]

2019.1990050.26402

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-7 Option for Increased Quantity – Separately Priced Line Item
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not, is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: 38-3412788
DUNS Number: 026489018
The purpose of this modification is to:

1. Order an increased quantity of [**] doses of [**] product at a unit price of $[**] per dose for a total cost of $[**].

2. Order an increased quantity of [**] doses of [**] product at a unit price of $[**] per dose for a total costs of $[**].

3. Accordingly, total contract value is hereby increased from $[**] by Continued…
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)* Michael Mann, Sr. Manager Comm. Ops.		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*) Caleb W. Owen	
15B. CONTRACTOR/OFFEROR /s/ J. Michael Mann II *(Signature of person authorized to sign)*	15C. DATE SIGNED 02 JAN 19	16B. UNITED STATES OF AMERICA By Makoto P. Braxton – S *(Signature of Contracting Officer)*	16C. DATE SIGNED

NSN 7540-01-152-8070 STANDARD FORM 30 (Rev. 10-83)
Previous edition unusable Sponsored by GSA
FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 330303

ITEM No. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	$[**] to $[**]. Appr. Yr.: 2019 CAN: 1990050 Object Class: 26402 FOB: Origin Period of Performance: 01/19/2017 to 09/30/2021 Add Item 3 as follows: Optional Line Item 0003 BioThrax [**] product [**] upon date of delivery: [**] at a unit price of $[**] Quantity: [**] Unit Price: $[**] Total Value: $[**] Delivery Address: Contractor's Facility Delivery is estimated to occur by NLT [**] [**] Product [**] at date of delivery: [**] Quantity: [**] Unit Price: $[**] Total Value: $[**] Delivery Address: Contractor's Facility Delivery is estimated to occur by NLT [**] Overall Total Order Price: [**] Obligated Amount: $[**] Requisition No: OS232936, OS233064				
3					[**]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 | 2

2. AMENDMENT/MODIFICATION NO. 0016	3. EFFECTIVE DATE 01/14/2019	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*

6. ISSUED BY CODE	ASPR-BARDA	7. ADMINISTERED BY *(If other than Item 6)* CODE	ASPR-BARDA02
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*	(x)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 330303 Attn: DIANA EMERGENT BIODEFENSE OPERATIONS LANS 3500 N MARTIN LUTHER KING JR BLVD LANSING MI 489062933		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSD200201792634C
		10B. DATED *(SEE ITEM 13)* 12/08/2016
CODE 330303	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or
(c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER *(Specify type of modification and authority)* FAR 52.212-4(c) Changes

E. IMPORTANT: Contractor is not, is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to update the DUNS and address information for the assignee, Wells Fargo Bank.

FROM:

Wells Fargo Bank, National Association
301 South College Street, 14th Floor
MAC D1053-133
Charlotte, NC 28202
Continued…
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)	
Michael Mann, Sr. Manager Comm. Ops.		Caleb W. Owen	
15B. CONTRACTOR/OFFEROR /s/ J. Michael Mann II *(Signature of person authorized to sign)*	15C. DATE SIGNED 14 JAN 19	16B. UNITED STATES OF AMERICA Caleb W. Owen - S *(Signature of Contracting Officer)*	16C. DATE SIGNED

NAME OF OFFEROR OR CONTRACTOR
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 330303

ITEM No. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	DUNS Number: [**] TO: Wells Fargo Bank, National Association c/o Wells Fargo & Company 420 Montgomery St. San Francisco, CA 94104 DUNS Number: [**]. Period of Performance: 01/19/2017 to 09/30/2021				

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

LICENSE AGREEMENT

between

LIGHTLAKE THERAPEUTICS INC.

and

ADAPT PHARMA OPERATIONS LIMITED

Dated as of December 15, 2014

LICENSE AGREEMENT

This License Agreement (the "Agreement") is made and entered into effective as of December 15, 2014 (the "**Effective Date**") by and between Lightlake Therapeutics Inc., a Nevada corporation ("**Lightlake**"), and Adapt Pharma Operations Limited, an Irish limited company ("**Adapt**"). Lightlake and Adapt are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Lightlake owns or Controls certain intellectual property relating to the use of intranasal naloxone for a treatment to reverse opioid overdoses; and

WHEREAS, Lightlake wishes to license to Adapt, and Adapt wishes to license from Lightlake, through the license grants contemplated herein, such intellectual property rights to develop and commercialize Products (as defined below) in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE I
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**Adapt**" has the meaning set forth in the preamble hereto.

1.2 "**Adapt Applied Know-How**" means all Information Controlled by Adapt or any of its Affiliates as of the Effective Date or during the Term (other than as a result of the licenses granted by Lightlake to Adapt under this Agreement) and incorporated by Adapt in any Product prior to any termination of this Agreement (provided, however, that such Information is necessary or reasonably useful for the Development, manufacture or Commercialization of any Product).

1.3 "**Adapt Applied Patents**" means all of the Patents Controlled by Adapt or any of its Affiliates as of the Effective Date or during the Term (other than as a result of the licenses granted by Lightlake to Adapt under this Agreement) that claim any Adapt Applied Know-How or claim or cover a Product.

1.4 "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with", means (i) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management or policies of such entity.

1.5 "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity.

1.6 "**[**] Unit Dose Device**" means that certain nasal unit-dose spray device sold by [**] Inc. or its Affiliates.

1.7 "**Business Day**" means a day other than a Saturday or Sunday on which banking institutions in New York, New York and Ireland are open for business.

1.8 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.9 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.10 "**Change in Control**" means with respect to a Party: (1) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (2) a merger, reorganization or consolidation involving such Party in which the holders of voting securities of such Party outstanding immediately prior thereto cease to hold voting securities that represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (3) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Party.

1.11 "**Commercial Sublicensee**" means a Sublicensee to whom Adapt has granted a right to offer for sale, have sold or sell one or more Products in all or a portion of the Territory including exclusive distributors, but excluding (i) Persons who Manufacture Product(s) or any element thereof and sell such Product(s) only to or at the direction of Adapt, Sublicensees or any of their respective Affiliates, (ii) wholesalers, (iii) pharmacies, (iv) Persons comprising the First Responder Market, (v) any Person performing third party logistics or warehousing services on behalf of Adapt or its Affiliates or Sublicensees, and (v) any other Person to whom Adapt has not relinquished material control over commercial decision-making in respect of the applicable Products and where such Person does not have any obligation to make an upfront, milestone or royalty payment with respect to the applicable Products.

1.12 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Product, including activities related to marketing, promoting, distributing, and importing such Product, and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

1.13 "**Commercialization Costs**" means the out-of-pocket costs and expenses incurred by Adapt or its Affiliates directly attributable to, or reasonably allocable to, the Commercialization of a Product. Commercialization Costs for a Product shall include, preparation of promotional, advertising, communication, medical, and educational materials relating to the Product and other Product literature and selling materials, activities directed to marketing of the Product, including purchase of market data, development and conduct of market research, advertising, public relations, public affairs and other communications with Third Parties regarding the Product; development and conduct of sales force training (including materials, programs and travel to and attendance at training programs) for medical representatives responsible for promoting the Product; and development and maintenance of sales bulletins, call reporting and other monitoring/tracking, sales force targeting, validation and alignment programs and documentation.

1.14 "**Commercially Reasonable Efforts**" means, with respect to the objective that is the subject of such efforts, such reasonable, good faith efforts and resources as a similarly-situated (including in relation to size and personnel and other resources) company within the pharmaceutical industry would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that, with respect to the Development and Commercialization of a Product by Adapt, such efforts shall take into account the Product's safety and efficacy, its cost to Develop, the competitiveness of alternative products marketed by or being developed by Third Parties and the nature and extent of market exclusivity (including Patent coverage and regulatory exclusivity), the likelihood of obtaining Regulatory Approval, the expected or actual pricing, reimbursement and formulary status, the Product's expected or actual profitability, including the amounts of marketing and promotional expenditures with respect to such Product and all other relevant factors with respect to the market for the Product, on a country-by-country basis.

1.15 "**Confidential Information**" means any technical, business, or other information or data provided orally, visually, in writing or other form by or on behalf of one Party to the other Party in connection with this Agreement (including any information provided under either that certain Mutual Non-Disclosure Agreement between the Parties dated May 1, 2014 or that certain Three-Way Confidential Disclosure Agreement among Lightlake, Adapt Pharma Operations Limited and [**] dated August 13, 2014 collectively, ("**Existing CDAs**"), including information relating to the terms of this Agreement, any Product (including the Regulatory Documentation), any Exploitation of any Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Lightlake Know-How and Adapt Applied Know-How, as applicable), or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, (i) all non-clinical, clinical, technical, chemical, safety, and scientific data and information and other results, and results of test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control activities and statistical analysis, including relevant laboratory notebook information, screening data, and synthesis schemes, including descriptions in any form, data and other Information relating to or resulting from the conduct of Development of Products after the Effective Date, or relating to or resulting from the pharmacokinetics study in respect of a Product commenced or commissioned by or at the direction of Lightlake prior to the Effective Date (the "**Pharmacokinetic Data**"), shall be Confidential Information of Adapt and (ii) subject to the foregoing clause (i), Joint Know-How shall be deemed to be the Confidential Information of both Parties.

1.16 "**Control"** means, with respect to any item of Information, Regulatory Documentation, material, Patent, or other property right existing on or after the Effective Date and during the Term, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 4.1 or 4.2), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent, or other property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.17 "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, "**Develop**" means to engage in Development.

1.18 "**Development Costs**" means the out-of-pocket costs and expenses incurred by a Party or its Affiliates directly attributable to, or reasonably allocable to, the Development of a Product, including costs and expenses associated with obtaining and/or Manufacturing product and materials utilized in clinical trials, submission batches or in connection with process validation, scale-up or otherwise required for purposes of obtaining Regulatory Approval.

1.19 "**Development Data**" means all non-clinical, clinical, technical, chemical, safety, and scientific data and information and other results, including relevant laboratory notebook information, screening data, and synthesis schemes, including descriptions in any form, data and other information, in each case, that is generated by or resulting from or in connection with the conduct of Development of Products, to the extent that the same are Controlled by or in Adapt's or its Affiliates' or Adapt's Commercial Sublicensees' possession, and may be disclosed to Lightlake without violating any obligation under Applicable Law.

1.20 "**Dollars**" or "**$**" means United States Dollars.

1.21 "**Drug Approval Application**" means a New Drug Application (an "**NDA**") as defined in the FFDCA, or any corresponding foreign application, including, with respect to the European Union, a Marketing Authorization Application (a "**MAA**") filed with the EMA or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.22 "**Effective Date**" means the effective date of this Agreement as set forth in the preamble hereto.

1.23 "**EMA**" means the European Medicines Agency and any successor agency or authority having substantially the same function.

1.24 "**Existing Inventory Supply**" means Lightlake's existing inventory of naloxone, excipients, devices and packaging set forth on Schedule 1.24 to be transferred to Adapt in accordance with Section 3.6.1 and the Initial Development Plan.

1.25 "**Exploit**" means to make, have made, import, use, sell, or offer for sale, including to research, Develop, Commercialize, Manufacture, have Manufactured, obtain Regulatory Approval for, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of on a worldwide basis. "**Exploitation**" shall mean the act of Exploiting.

1.26 "**FDA**" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.27 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.28 "**First Commercial Sale**" means, with respect to a Product and a country, the first sale by Adapt, its Affiliate or its Commercial Sublicensee to a Third Party for monetary value of such Product in such country after Regulatory Approval for such Product has been obtained in such country; provided, however, no sale comprising the Limited Purdue Sales shall be deemed a "First Commercial Sale" for purposes hereof.

1.29 "**First Responder Market**" means governmental agencies, non-profit institutions and medical directors that prescribe on behalf of an organization for use by fire, police, emergency medical personnel, military or similar personnel that act as first responders, but excluding hospitals and clinics and any Person acquiring Products through retail channels.

1.30 "**Generic Product**" means, with respect to a Product, any intranasal product in an intranasal device that (i) is sold by a Third Party that is not a licensee or a Commercial Sublicensee of Adapt or its Affiliates, under an Abbreviated New Drug Application (ANDA), or any of such Third Party's direct or indirect licensees or sublicensees; (ii) contains naloxone as the primary active ingredient; and (iii) is approved in reliance, in whole or in part, on the prior approval of such Product. A Product licensed or produced by Adapt or its Affiliates or Commercial Sublicensees (i.e., an authorized generic product) will not constitute a Generic Product.

1.31 "**IND**" means an application filed with a Regulatory Authority for authorization to commence human clinical studies, including (a) an Investigational New Drug Application as defined in the FFDCA or any successor application or procedure filed with the FDA, (b) any equivalent of a United States IND in other countries or regulatory jurisdictions, and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.32 "**Information**" means all technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays, biological methodology, other data relating to Development, all data, information and materials relating to Commercialization, including customer lists (both actual and target customers), any market studies and competitive data; in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.33 "**Initial Development Plan**" means the initial Development Plan (including the Development budget) attached hereto as Schedule 1.33 covering the initial Development activities, as the same may be amended from time to time in accordance with the terms hereof.

1.34 "**Invention**" means any writing, invention, discovery, improvement, technology, Information or other Know-How (in each case, whether patented or not) that is not existing as of the Effective Date and is invented under this Agreement during the Term.

1.35 "**LIBOR**" means the London Interbank Offered Rate for deposits in United States Dollars having a maturity of one month published by the British Bankers' Association, as adjusted from time to time on the first London business day of each month.

1.36 "**Liens**" means any and all liens, encumbrances, charges, security interests, options, claims, mortgages, pledges, or agreements, obligations, understandings or arrangements or other restrictions on title or transfer of any nature whatsoever.

1.37 "**Lightlake**" has the meaning set forth in the preamble hereto.

1.38 "**Lightlake Know-How**" means all Information Controlled by Lightlake or any of its Affiliates as of the Effective Date or at any time during the Term (subject to Section 11.3.2) that is not generally known and is necessary or reasonably useful for the Development, manufacture, or Commercialization of a Product, but excluding any Information to the extent covered or claimed by published Lightlake Patents or Joint Patents or any Joint Know-How.

1.39 "**Lightlake Patents**" means all of the Patents Controlled by Lightlake or any of its Affiliates as of the Effective Date or at any time during the Term (subject to Section 11.3.2) that claim or disclose the Development, Manufacture, or Commercialization of a Product, but excluding any Joint Patents, and excluding the Product Specific Patents.

1.40 "**Limited Purdue Sales**" means the sale of such number of units of Product(s) that Adapt is obligated to sell to or at the direction of Purdue pursuant to the Purdue Agreement, up to either (i) such number of units having an aggregate fair market value of fifty thousand dollars or (ii) an aggregate of 2,500 units (of two doses each), which ever is greater. For clarity, sales of Products to Purdue in excess of the foregoing number of units shall not be included in Limited Purdue Sales.

1.41 "**MAA**" has the meaning set forth in the definition of "Drug Approval Application."

1.42 "**Major Market**" means each of France, Germany, Italy, Spain or United Kingdom.

1.43 "**Manufacture**" or "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of a Product or any intermediate thereof, including clinical and commercial manufacture.

1.44 "**NDA**" has the meaning set forth in the definition of "Drug Approval Application."

1.45 "**Net Sales**" means, with respect to a Product for any period, the total amount billed or invoiced on sales of such Product during such period by Adapt, its Affiliates, or Sublicensees to Third Parties, less the following normal and customary bona-fide deductions and allowances actually taken:

1.45.1 trade, cash and quantity discounts;

1.45.2 price reductions, refunds or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid (whether in cash or trade) to governmental authorities or third party payors;

1.45.3 taxes on sales (such as sales, value added, or use taxes) and customs and excise duties and other duties related to sale, in each case, to the extent such taxes are included in the gross amount invoiced;

1.45.4 wholesale and distribution fees, deductions and prompt pay discounts;

1.45.5 bad debts not exceeding five percent (5%) of the value of the sales of Product during the then-current Calendar Year, provided that any recovery of bad debts shall be deemed a sale for purposes of this definition of "Net Sales";

1.45.6 amounts repaid, deducted or credited by reason of rejections, defects, recalls or returns, or because of retroactive price reductions, including rebates or wholesaler charge backs; and

1.45.7 freight, insurance, and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced. Notwithstanding the foregoing, Net Sales shall not include (i) transfers or dispositions for charitable, pre-clinical, clinical, regulatory, or governmental purposes or (ii) sales or transfers comprising the Limited Purdue Sales. To the extent that Adapt, its Affiliate or any Commercial Sublicensee sells a Product, on an arms-length basis, to any Sublicensee who is not an Affiliate of such selling Person for resale, only the initial sale of such Product by Adapt, its Affiliate, or its Commercial Sublicensee shall constitute a sale for purposes of determining Net Sales. Except as contemplated by the immediately foregoing sentence, Net sales shall not include sales between or among Adapt, its Affiliates, or Sublicensees. Net Sales shall be calculated in accordance with the standard internal policies and procedures of Adapt, its Affiliates, or Sublicensees, which must be in accordance with United States Generally Accepted Accounting Principles or International Financial Reporting Standards as applicable. If Adapt (or any of its Affiliates or Sublicensees) for a given Product sells such Product to a Third Party (including distributors) who also purchases other products or services from any such entity, then Adapt agrees not to, and shall require its Affiliates and Sublicensees not to, (a) bundle or include the Product as part of any multiple product offering or (b) discount or price the Product, in the case of either of the foregoing clauses (a) or (b), in a manner that is reasonably likely to disadvantage such Product in order to benefit sales or prices of other products offered for sale by Adapt or its Affiliates or Sublicensees to such customer.

1.46 **"NIDA"** means The Division of Pharmacotherapies and Medical Consequences of Drug Abuse of the National Institute on Drug Abuse.

1.47 **"NIDA Agreement"** means that certain Clinical Trial Agreement, dated January 31, 2013, between Lightlake and NIDA.

1.48 "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

1.49 "**Patents**" means (i) all national, regional and international patents and patent applications, including provisional patent applications; (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents and design patents and certificates of invention; (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii), and (iii)); and (v) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.50 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, foundation, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.51 "**Product**" means any pharmaceutical product or medical device, whether prescription or over-the-counter, marketed for a treatment of opioid overdose containing naloxone, alone or in combination with one or more other active or inactive ingredients, in any intranasal form, presentation, strength or delivery systems; provided, however, that "Product" shall not refer to any product Controlled, developed, manufactured, marketed, sold, offered for sale, exported, or imported directly or indirectly by a Sublicensee if such Sublicensee's rights in respect of such product were obtained or developed independently of any sublicense or right granted by Adapt hereunder.

1.52 "**Product Specific Patents**" means those Patents set forth on Schedule 1.52.

1.53 "**Product Trademarks**" means the Trademark(s) to be used by Adapt or its Affiliates or its or their respective Sublicensees for the Commercialization of Products and any registrations thereof or any pending applications relating thereto (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates).

1.54 **"Purdue"** means Purdue Pharma LP or such Affiliate of Purdue Pharma LP that is the initial party to the Purdue Agreement, or any assignee or successor to such Person's rights or obligations under the Purdue Agreement.

1.55 **"Purdue Agreement"** means the license agreement to be entered into by Lightlake or Adapt or one of their Affiliates with Purdue Pharma LP based upon the term sheet between Lightlake and Purdue Pharma LP dated September 24, 2014.

1.56 "**Regulatory Approval**" means, with respect to a country or other jurisdiction, any and all approvals (including Drug Approval Applications), licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, offer for sale, market, import or use a Product in such country or other jurisdiction, including, where applicable, (i) pricing or reimbursement approval in such country or other jurisdiction, (ii) pre-and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (iii)labeling approval.

1.57 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory agencies, departments, bureaus, commissions, councils, or other government entities (e.g., the FDA and EMA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the Exploitation of Products.

1.58 "**Regulatory Costs**" means the out-of-pocket costs and expenses incurred by a Party or its Affiliates in connection with the preparation, obtaining or maintaining of Regulatory Documentation and Regulatory Approvals for the Product, including any filing fees that are consistent, if applicable, with the Development Plan.

1.59 "**Regulatory Documentation**" means all (i) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations, and approvals (including Regulatory Approvals); (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files; and (iii) clinical and other data contained or relied upon in any of the foregoing, in each case ((i), (ii), and (iii)) relating to a Product.

1.60 "**Senior Officer**" means, with respect to Lightlake, its Chief Executive Officer or his/her designee or his/her designee, and with respect to Adapt, its Chief Executive Officer or Chief Operating Officer or his/her designee.

1.61 "**Sublicensee**" means a Person, other than an Affiliate, that is granted a sublicense by Adapt under a license granted in Section 4.1 or a right by Adapt, its Affiliates or Commercial Sublicensees to sell a Product, offer a Product for sale, or have a Product sold (each such sublicense or right, a "Sublicense").

1.62 "**Third Party**" means any Person other than Lightlake, Adapt and their respective Affiliates.

1.63 "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.64 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

Additional Definitions. The following terms have the meanings set forth in the corresponding Sections of this Agreement:

Term	Section
"Adapt Indemnitees"	9.2
"Annual Net Sales Milestone Threshold"	5.3.1
"Annual Net Sales-Based Milestone Table"	5.3.1
"Annual Net Sales-Based Milestone Payment"	5.3.1
"Annual Net Sales-Based Milestone Payment Date"	5.3.1
"Audit Arbitrator"	5.13.2
"Breaching Party"	10.3
"Competing Product"	4.6
"Core IP"	5.5
"Default Notice"	10.3
"Development Plan"	3.1
"Follow-On Product"	5.2.5
"Force Majeure"	11.1
"First Product"	5.2.6
"Generic Competition"	5.4.2
"Indemnification Claim Notice"	9.3
"Indemnified Party"	9.3
"Initial First Responder Sales"	5.4.1
"Joint Development Committee" or "JDC"	2.1
"Joint Know-How"	6.1.2
"Joint Patents"	6.1.2
"Joint Intellectual Property Rights"	6.1.2
"Lightlake Cost Cap"	3.8.1
"Lightlake Indemnitees"	9.1
"Losses"	9.1
"Non-Breaching Party"	10.3
"Payment"	5.8
"Pharmacokinetic Data"	1.15
"Reconciliation Development Payment"	5.11.2
"Recovery"	6.4.3(d)
"ROFN"	4.3.3
"Sublicense"	1.61
"Target Filing Date"	3.2.3
"Term"	10.1
"Third Party Claims"	9.1

ARTICLE II
JOINT DEVELOPMENT COMMITTEE

2.1 Formation. Within fifteen (15) days after the Effective Date, the Parties shall establish a joint development committee (the "**Joint Development Committee**" or "**JDC**"). The JDC shall consist of relevant representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JDC. Each Party shall be entitled to appoint up to two (2) representatives to the JDC. From time to time, each Party may substitute one (1) or more of its representatives to the JDC on written notice to the other Party. Adapt shall designate from its representatives the chairperson for the JDC. From time to time, Adapt may change the representative who will serve as chairperson on written notice to Lightlake.

2.2 Specific Responsibilities. The JDC shall meet monthly in person or by phone for the purpose of facilitating the transition of Development of the Product from Lightlake to Adapt. At least seven (7) days prior to each meeting, each Party shall circulate an agenda of items that such Party wishes to cover in such meeting. In particular, the JDC shall:

2.2.1 review and serve as a forum for discussing the Initial Development Plan, and review amendments thereto;

2.2.2 oversee any transition activities under the Initial Development Plan;

2.2.3 serve as a forum for discussing strategies for obtaining Regulatory Approvals for Products; and

2.2.4 perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.3 Disbandment. Upon the [**] anniversary of the Effective Date, the JDC shall have no further responsibilities or authority under this Agreement and will be considered dissolved by the Parties.

2.4 Decision Making. If the JDC cannot, or does not, reach consensus on an issue at a particular meeting, Adapt shall make the decision; provided; however, that Adapt may not exercise its decision making authority in a manner that would increase Lightlake's full-time employee obligations under the Initial Development Plan, significantly modify the types of activities that Lightlake would have to perform under the Initial Development Plan, extend Lightlake's period of performance more than [**] months after the Effective Date or increase the Lightlake Cost Cap.

2.5 Limitations on JDC Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the JDC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The JDC shall not have the power to amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 11.9 or compliance with which may only be waived as provided in Section 11.11.

ARTICLE III
DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES

3.1 Development Plan.

3.1.1 Development Plan Delivery. By no later than November 1st of each Calendar Year during the Term after the Calendar Year in which the Initial Development Plan was delivered until First Commercial Sale of a Product in the United States, Adapt shall prepare a written development plan that describes generally the material Development activities to be undertaken by or on behalf of Adapt with respect to Products in the next Calendar Year (each, a "**Development Plan**"), and each such Development Plan shall be provided to Lightlake and Adapt shall consider any comments of Lightlake in good faith. The Initial Development Plan shall serve as the Development Plan for the first full Calendar Year of this Agreement and the period from the Effective Date through the end of the initial partial Calendar Year. Without limiting the generality of the foregoing, each Development Plan shall set forth, among other things and to the extent relevant based on the stage of Development, the following with respect to the Products then under Development:

(a) any preclinical studies, toxicology studies and other clinical studies with respect to Products;

(b) regulatory plans and other elements of obtaining and maintaining Regulatory Approvals for Products;

(c) the plans and timeline for preparing the necessary Regulatory Documentation and for obtaining Regulatory Approval for Products.

3.1.2 Development Plan Amendments. Adapt may amend any Development Plan at any time, subject to providing Lightlake an opportunity to discuss any proposed revisions prior to making such amendment and, during the first twelve (12) months following the Effective Date, by submitting such amendment to the JDC prior to such amendment becoming effective; provided, however, that no such amendment to any Development Plan may provide for an increase in Lightlake's full-time employee obligations under the Initial Development Plan, significantly modify the types of activities that Lightlake would have to perform under the Initial Development Plan, extend Lightlake's period of performance more than twelve (12) months after the Effective Date or increase the Lightlake Cost Cap.

3.2 Development.

3.2.1 Ongoing Development. The Parties acknowledge and agree that additional Development will be required to obtain Regulatory Approvals for Products. After the Effective Date, as between the Parties, except as set forth in the Initial Development Plan (as the same may be amended in accordance with Section 3.1.2) and Section 3.8.1, Adapt shall be solely responsible for Development of the Products.

3.2.2 General Diligence. Adapt shall use Commercially Reasonable Efforts to complete the activities associated with the Development of the initial Product for the United States that are contemplated by the Development Plan then in effect (other than any such activities to be undertaken by Lightlake). Adapt shall, and shall cause its Affiliates to, comply with all Applicable Law with respect to Products.

3.2.3 Specific Diligence Requirement. Without limiting the foregoing, if Adapt has not filed an NDA in respect of a Product on or before the Target Filing Date, Adapt shall be deemed to be in material breach of this Agreement unless:

(a) Adapt shall have theretofore completed those tasks in relation to the Development of a Product contemplated on Schedule 3.2.3(a) hereto; or

(b) the aggregate amount of Development Costs, Regulatory Costs and Commercialization Costs theretofore incurred by Adapt and Lightlake after the Effective Date, together with the costs and expenses set forth on Schedule 3.8.2 hereto, shall equal or exceed $5 million; or

(c) prior to such time, a Third Party files a Drug Approval Application in the United States for an intranasal product for the treatment of opioid overdose and, either (i) such product has the same dosage form as the Product being developed by Adapt or (ii) such product is deemed by the FDA to be, or otherwise becomes, the reference drug for purposes of any NDA that would be filed under Section 505(b)(2) of the FFDCA in respect of the Product being developed by Adapt; or

(d) any other circumstances that the Parties have separately agreed in writing will constitute exceptions pursuant to this Section 3.2.3 occur or exist.

For clarity, if any of the circumstances contemplated by clauses (a) through (c) above exist, Adapt shall not be deemed to be in breach of this Agreement by virtue of its failure to file an NDA for a Product on or prior to the Target Filing Date, but shall remain subject to the obligation to use Commercially Reasonable Efforts in respect of the Development of the initial Product, as set forth above in Section 3.2.2. In the event that none of the circumstances contemplated above exist, but Adapt notifies and provides reasonable evidence to Lightlake that such inability to file on or prior to the Target Filing Date is due to variables outside of Adapt's reasonable control, Adapt may request that Lightlake consent to an extension of such Target Filing Date and Lightlake shall not unreasonably withhold, delay or condition such requested extension. "**Target Filing Date**" means the date specified in the Initial Development Plan as the date by which Adapt shall file an NDA in respect of a Product or such later date as Lightlake may consent to in accordance with the immediately preceding sentence, provided that in the event of (i) a delay in the Development of a Product that is caused by a Third Party and outside the reasonable control of Adapt or (ii) a Force Majeure, then (in either case, clause (i) or (ii)) the Target Filing Date shall automatically be extended by the actual amount of delay caused by a Third Party or the duration of the Force Majeure, respectively. For clarity, Adapt shall not be in material breach of its Development Obligations under this Agreement, including by virtue of this Section 3.2.3, if the Target Filing Date has been extended pursuant to this paragraph of Section

3.2.4 unless Adapt fails to file an NDA in respect of a Product on or before the revised Target Filing Date.

3.2.5 **Development Costs**. Except as otherwise provided in Section 3.8.1, Adapt shall be responsible for all costs and expenses in connection with the Development of Products.

3.2.6 **Interactions with Third Parties**. Except as otherwise expressly contemplated by this Agreement or the Development Plan, or as expressly agreed between the Parties, as between the Parties, Adapt shall be solely responsible for and shall control, all interactions with Third Parties regarding the Development, Manufacturing and Commercialization of the Products.

3.3 Regulatory Matters.

3.3.1 **Regulatory Activities.**

(a) As between the Parties, Adapt shall be responsible for preparing, obtaining, and maintaining Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions, and for conducting communications with the Regulatory Authorities, for Products (which shall include filings of or with respect to INDs and other filings or communications with the Regulatory Authorities), in each case in accordance with the terms of this Agreement and otherwise in Adapt's sole discretion. All Regulatory Approvals applied for or received after the Effective Date relating to Products shall be owned by and held in the name of, Adapt. At Adapt's request, Lightlake shall transfer ownership of the IND in respect of the initial Product to Adapt at no cost and shall take such action as is necessary to confirm such transfer with the FDA.

(b) Adapt shall notify Lightlake promptly (but in no event later than forty-eight (48) hours) following its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Product, and shall include in such notice the reasoning behind such determination, and any supporting facts. Adapt (or its Sublicensee) shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority, Adapt (or its Sublicensee) shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions, or market withdrawals undertaken, Adapt (or its Sublicensee) shall be solely responsible for the execution and all costs thereof.

3.3.2 **Regulatory Costs**. Except as otherwise provided in Section 3.8.1, Adapt shall be responsible for all costs and expenses in connection with the Development of, and obtaining and maintaining Regulatory Approvals for, Products.

3.3.3 Rights of Reference and Access to Data.

(a) Adapt shall have the right to cross-reference Lightlake's or its Affiliate's Regulatory Approvals and Regulatory Documentation related to Products, and to access such Regulatory Approvals and Regulatory Documentation and any data and know-how therein and use such data and know-how, in each case in connection with the performance of its obligations and exercise of its rights under this Agreement. Lightlake hereby grants to Adapt a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other jurisdiction, to any data, including Lightlake's or its Affiliates' Regulatory Approvals and Regulatory Documentation, that relate to a Product for use by Adapt to Develop and Commercialize Products pursuant to this Agreement. Lightlake or such Affiliate shall provide a signed statement to this effect, if requested by Adapt, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any other jurisdiction or otherwise provide appropriate notification of such right of Adapt to the applicable Regulatory Authority.

(b) Upon and subject to the Parties' mutual written agreement upon commercially reasonable terms, Adapt shall (a) grant Lightlake the right to cross-reference Adapt's or its Affiliate's or Commercial Sublicensee's Regulatory Approvals and Regulatory Documentation related to Products, and to access such Regulatory Approvals and Regulatory Documentation and any data and know-how therein and use such data and know-how, in each case in connection with the development, manufacture, use, and/or commercialization of intranasal products containing naloxone (other than Products) and (b) grant Lightlake a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other jurisdiction, to any data, including Adapt's or its Affiliates' or Commercial Sublicensee's Regulatory Approvals and Regulatory Documentation, that relate to a Product for use by Lightlake to development, manufacture, use, and/or commercialization of intranasal products containing naloxone (other than Products). For the sake of clarity, this Section 3.3(b) shall be of no force or effect unless and until the Parties agree in writing on the terms of such foregoing rights. Notwithstanding the foregoing, Adapt shall promptly provide Lightlake the Pharmacokinetic Data upon it becoming available, provided that

Lightlake shall not have a right to use such data or reference such data for any purpose other than with respect to its indemnification obligations under this Agreement.

3.4 Records; Reports. Adapt shall maintain records in reasonable detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law, which shall be materially complete and accurate and shall properly reflect all material work done and results achieved in the performance of its Development activities in respect of the Products. Following the first anniversary of the Effective Date, Adapt and Lightlake shall meet at least once and up to twice per annum, at such times as the Parties shall reasonably agree to discuss the then-ongoing Development and Commercialization activities that (i) Adapt is undertaking with respect to Products and (ii) Lightlake is undertaking in respect of other products containing naloxone. At each such meeting, (x) Adapt shall update Lightlake on the material developments in respect of its Development and Commercialization of Products and discuss in good faith any suggestions or questions Lightlake may have and Lightlake shall be permitted to retain a copy of Adapt's presentation materials, subject to Article 7 hereof and (y) Lightlake shall update Adapt on the material developments in Lightlake's and its other licensees' efforts to Develop and Commercialize such other naloxone products, subject to Article 7 hereof.

3.5 Commercialization.

3.5.1 In General. Except as otherwise provided in Section 3.8.1, Adapt (itself or through its Affiliates or Sublicensees) shall be solely responsible for Commercialization of Products at Adapt's own cost and expense, in accordance with the terms of this Agreement and otherwise in Adapt's sole discretion.

3.5.2 Diligence. Once a Product receives all requisite Regulatory Approvals in a particular country necessary to Commercialize such Product in such country, Adapt shall use Commercially Reasonable Efforts to Commercialize such Product in such country. Adapt shall Commercialize Products in accordance with Applicable Law. Without limiting any of the foregoing, on a Product-by-Product basis, Adapt shall use Commercially Reasonable Efforts to achieve First Commercial Sale of a Product in the United States within nine (9) months after the date on which Adapt is notified by the FDA that an NDA in respect of such Product has received approval.

3.5.3 Booking of Sales; Distribution. As between the Parties, Adapt shall invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Products and perform or cause to be performed all related services. As between the Parties, Adapt shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Products.

3.5.4 Product Trademarks. Adapt shall have the sole right to determine, in its sole discretion, the Product Trademarks to be used with respect to the Exploitation of Products on a worldwide basis. As between the Parties, all such Product Trademarks shall be owned by Adapt.

3.6 Supply of Products.

3.6.1 Assignment of Existing Inventory. Subject to Section 3.8.3, Lightlake hereby sells and assigns to Adapt all of its right, title, and interest in and to the Existing Inventory Supply. Lightlake shall not be entitled to any additional payment for such Existing Inventory. Promptly following the Effective Date, Lightlake shall deliver or have delivered such supply to Adapt FCA (Incoterms 2010) the facility designated by Adapt.

3.6.2 Supply of Products. Except as set forth in Section 3.6.1, as between the Parties, subject to Section 3.8.1, Adapt shall have the sole responsibility for, at its expense, Manufacturing (or having Manufactured) and obtaining supply of naloxone (including all excipients) and devices (including packaging) for pre-clinical and clinical purposes and for commercial sale of Products by Adapt and its Affiliates and Commercial Sublicensees. Adapt shall use Commercially Reasonable Efforts to ensure that any agreement pursuant to which Adapt contracts with Third Parties for the supply of the device utilized by the Products and of finished Products may be assigned to Lightlake without such Third Party's consent in the event that this Agreement is terminated.

3.7 Subcontracting; Assigned Contracts. Either Party may subcontract with a Third Party to perform any or all of its obligations hereunder, *provided* that (i) no such permitted subcontracting shall relieve a subcontracting Party of any liability or obligation hereunder except to the extent satisfactorily performed by such subcontractor, and (ii) the Party engaging such subcontractor shall ensure that the agreement pursuant to which the subcontracting Party engages such subcontractor (A) does not conflict with any material term of this Agreement, and (B) contains terms obligating such subcontractor to comply with obligations of confidentiality and non-use consistent with those set forth in this Agreement. Promptly after the Effective Date, Lightlake shall use commercially reasonable efforts to assign to Adapt, and for Adapt to assume from Lightlake all of Lightlake's right, title, and interest in and to the Third Party contracts set forth on Schedule 3.7 (the "**Assigned Contracts**"), including (a) by obtaining from each Third Party counterparty thereto a consent in the form attached hereto as Exhibit A and (b) entering into one or more assignment and assumption agreements substantially in the form attached hereto as Exhibit B. In addition, as soon as practicable following the Effective Date (1) the Parties shall meet with NIDA to discuss the transition of the Development of the initial Product to Adapt as contemplated herein and (2) [**].

3.8 Sharing of Development Costs, Regulatory Costs and Commercialization Costs.

3.8.1 Cost Sharing. Lightlake shall bear fifty percent (50%) of all Development Costs and Adapt shall bear fifty percent (50%) of all Development Costs (whether incurred by Lightlake or Adapt or their respective Affiliates, Sublicensees or subcontractors) incurred after the Effective Date in accordance with the Development Plan in connection with the Development of Products using the [**] Unit Dose Device and Lightlake shall bear fifty percent (50%) of all Regulatory Costs and Commercialization Costs incurred by Adapt and Adapt shall bear fifty percent (50%) of all Regulatory Costs and Commercialization Costs incurred by Adapt (whether incurred by Adapt or its Affiliates, Sublicensees or subcontractors), in connection with the Development and Commercialization of the Product using the [**] Unit Dose Device until such time as Lightlake has incurred Development Costs, Regulatory Costs and Commercialization Costs of Two Million Five Hundred Thousand Dollars ($2,500,000) (the "**Lightlake Cost Cap**"). After the Lightlake Cost Cap has been reached, Adapt shall be responsible for one hundred percent (100%) of all Development Costs, Regulatory Costs and Commercialization Costs. For clarity, Lightlake shall not have any obligation to bear any Development Costs, Regulatory Costs or Commercialization Costs in connection with the Development or Commercialization of a Product using a drug delivery device other than the [**] Unit Dose Device; provided, however, in the event that Adapt determines, in good faith, that the Product cannot be further Developed using the [**] Unit Dose Device, whether due to a technical failure or failure of any clinical study using such device, then Adapt may proceed with Development using another device and the foregoing cost sharing provisions shall apply to the Development Costs, Regulatory Costs and Commercialization Costs associated with such alternate Product as well. Notwithstanding the foregoing, Development Costs incurred by Lightlake (or its Affiliates, Sublicensees or subcontractors) shall only be shared and credited towards the Lightlake Cost Cap in accordance with this Section 3.8.1 to the extent the same are either (a) contemplated in the Initial Development Plan or a subsequent Development Plan and are expressly approved in advance by Adapt, or are set forth on Schedule 3.8.2 or (b) paid by Lightlake after the Effective Date to suppliers and/or vendors, including their affiliates, whose names are listed on Schedule 3.8.2, other than [**], for activities related exclusively to the

Product where such activities commenced before the Effective Date; provided, however, that the aggregate amount contemplated by this clause (b) shall not exceed $150,000.

3.8.2 Crediting of Certain Costs. The Parties agree that the costs and expenses incurred by Lightlake prior to the Effective Date in respect of the Development of the initial Product that are specified on Schedule 3.8.2 hereto shall be credited as Lightlake's payment of Development Costs in accordance with Section 3.8.1 and count towards the Lightlake Cost Cap. For clarity, if Adapt and its Affiliates and Sublicensees fail to incur Development Costs in excess of the amount credited hereunder for Lightlake's share of the Development Costs, Lightlake shall not be entitled to any payment from Adapt for such excess amounts.

3.8.3 Payment and Reimbursement of Costs. To the extent that either Party is entitled to a reimbursement of costs described in Section 3.8.1, such costs will be reconciled and paid in accordance with Section 5.11.

3.8.4 General. Each Party shall maintain current and accurate records of all costs and expenses incurred by it for which it seeks reimbursement from the other Party pursuant to Section 3.8.1.

ARTICLE IV
TRANSFER AND ASSIGNMENT; GRANT OF RIGHTS

4.1 Grants to Adapt. Subject to the terms and conditions of this Agreement, Lightlake hereby grants to Adapt an exclusive (including with regard to Lightlake) worldwide license, with the right to grant sublicenses in accordance with Section 4.4, under the Lightlake Patents, the Product Specific Patents, the Lightlake Know-How, and Lightlake's interests in the Joint Patents and the Joint Know-How, to Exploit Products.

4.2 Grants to Lightlake.

4.2.1 Adapt hereby grants to Lightlake a non-exclusive, royalty-free license, without the right to grant sublicenses, under the Adapt Applied Patents, the Adapt Applied Know-How, and Adapt's interests in the Joint Patents and the Joint Know-How solely for purposes of performing its obligations as set forth in, and subject to, this Agreement.

4.2.2 Upon and subject to agreement of commercially reasonable terms, Adapt shall grant to Lightlake a non-exclusive, royalty-free, worldwide license, with the right to grant sublicenses, under the Adapt Applied Patents, the Adapt Applied Know-How and Development Data to Develop, Manufacture and Commercialize products containing naloxone other than a Product. For the sake of clarity, this Section 4.2.2 shall be of no force or effect unless and until the Parties agree in writing on the terms of such foregoing rights.

4.3 Sublicenses.

4.3.1 Right to Grant Sublicenses. Adapt shall have the right to grant Sublicenses (through multiple tiers of Sublicensees). Adapt shall cause each Sublicensee to comply with the applicable terms and conditions of this Agreement. Adapt shall remain responsible for the performance of its Affiliates and Sublicensees that are granted Sublicenses as permitted herein, and the grant of any such Sublicense shall not relieve Adapt of its obligations under this Agreement. With respect to any such Sublicense, Adapt shall ensure that the agreement pursuant to which it grants such Sublicense (i) does not conflict with the terms and conditions of this Agreement and (ii) contains terms obligating the Sublicensee to comply with confidentiality and non-use provisions consistent with those set forth in this Agreement. With respect to any such Sublicense to a Commercial Sublicensee, Adapt shall use Commercially Reasonable Efforts to ensure that the agreement pursuant to which it grants such Sublicense contains (A) terms obligating such Commercial Sublicensee to permit Lightlake rights of inspection, access, and audit substantially similar to those provided to Lightlake in this Agreement and (B) terms relating to intellectual property and data ownership consistent with those set forth in this Agreement. With respect to any such Sublicense to a Commercial Sublicensee, Adapt shall ensure that the agreement pursuant to which it grants such sublicense contains an exclusivity provision consistent with that contained in Section 4.6.2. A copy of any Sublicense agreement with a Commercial Sublicensee executed by Adapt shall be provided to Lightlake within fourteen (14) days after its execution; *provided* that the financial terms of any such Sublicense agreement may be redacted to the extent not pertinent to an understanding of a Party's obligations or benefits under this Agreement.

4.3.2 Termination of Sublicenses. In the event of termination of this Agreement, in whole or in part, any sublicense granted by Adapt pursuant to this Section 4.3 shall automatically be deemed to terminate to the same extent as the license or other rights granted by Lightlake to Adapt in Section 4.2, and the other terms and conditions of this Agreement, terminate.

4.3.3 Right of First Negotiation. Notwithstanding anything to the contrary in this Agreement, in the event Lightlake elects to license, sublicense or sell (except in connection with a license or sale of all or substantially all of the assets of Lightlake), in one transaction or a series of related transactions, a controlling interest with respect to any product containing naloxone, Lightlake shall promptly provide notice to Adapt of such election and Lightlake hereby grants to Adapt a right of first negotiation to license or acquire such rights ("**ROFN**"). Adapt may exercise each ROFN upon notice to Lightlake within fifteen (15) Business Days from the date upon which Adapt receives written notice from Lightlake. In the event that Adapt elects to exercise a ROFN, the Parties shall enter into good faith negotiations for a commercially reasonable licensing or asset sale agreement. If the Parties, in good faith negotiations, are unable to reach agreement within seventy (70) days after the date upon which Adapt exercised the ROFN, then Lightlake will be free to enter an agreement for such rights with a Third Party.

4.4 Retention of Rights; Limitations Applicable to License Grants.

4.4.1 Retained Rights of Lightlake. Except as expressly set forth in this Agreement, and without limitation to any rights granted or reserved to Lightlake pursuant to any other term or condition of this Agreement, Lightlake hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensees, sublicensees and contractors):

(a) non-exclusive rights in and to the Lightlake Patents, the Lightlake Know-How, Lightlake's interests in and to Joint Patents and Joint Know-How, in each case solely to perform its obligations under this Agreement; and

(b) all right, title, and interest in and to the Lightlake Patents, the Lightlake Know-How, Lightlake's interests in and to Joint Patents and Joint Know-How, in each case to develop and obtain and maintain regulatory approvals for, and to manufacture, commercialize and otherwise exploit any compound or product other than Products or Competing Products.

4.4.2 **No Other Rights Granted by Lightlake**. Except as expressly provided herein and without limiting the foregoing, Lightlake grants no other right or license, including any rights or licenses to the Lightlake Patents, the Lightlake Know-How, the Regulatory Documentation, or any other Patent or intellectual property rights not otherwise expressly granted herein.

4.5 **Transfer of Lightlake Know-How**. As soon as practicable after the Effective Date, Lightlake shall provide to Adapt (which can be in the form of copies and electronic files) all material Lightlake Know-How existing as of the Effective Date, to the extent such Lightlake Know-How has not theretofore been provided to Adapt and is reasonably required by or useful to Adapt for the exercise of its rights or the performance of its obligations under this Agreement.

4.6 **Exclusivity.**

4.6.1 During the Term and for a period of one year following the Term, other than as contemplated by this Agreement, neither Party shall, and each Party shall cause its Affiliates not to and shall use Commercially Reasonable Efforts to cause its directors, officers and employees not to, (i) directly or indirectly, develop, commercialize or manufacture any product containing naloxone as the active ingredient for the treatment of opioid overdose in an intranasal form ("**Competing Product**") in any country or other jurisdiction, or (ii) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly, develop, commercialize or manufacture any Competing Product in any country or other jurisdiction.

4.6.2 During the term of any agreement pursuant to which a Commercial Sublicensee is granted a Sublicense to sell a Product or have a Product sold, other than as contemplated by this Agreement, each Party shall cause its Commercial Sublicensees not to (i) directly or indirectly, develop, commercialize or manufacture any Competing Product in any country or other jurisdiction in which such Commercial Sublicensee has been granted a Sublicense to sell a Product or have a Product sold, or (ii) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly, develop, commercialize or manufacture any Competing Product in any such country or other jurisdiction in which such Commercial Sublicensee has been granted a Sublicense to sell a Product or have a Product sold.

4.7 **Compliance with Law**. Adapt shall conduct, or cause to be conducted, the Development, Commercialization, Manufacture and Exploitation of Products in compliance with all Applicable Laws.

ARTICLE V
PAYMENTS AND RECORDS

5.1 **Upfront Payment**. Within one (1) Business Days after the Effective Date, Adapt shall pay Lightlake an upfront amount equal to Five Hundred Thousand Dollars ($500,000). Such payment shall be nonrefundable and noncreditable against any other payments due hereunder.

5.2 **Regulatory Milestones**. In partial consideration of the rights granted by Lightlake to Adapt hereunder and subject to the terms and conditions set forth in this Agreement, Adapt shall pay to Lightlake a milestone payment within thirty (30) days after the achievement of each of the following milestones:

5.2.1 Adapt's first receipt of notice from the FDA that an NDA in respect of a Product has received approval, [**] Dollars ($[**]);

5.2.2 First Commercial Sale of a Product in the United States, [**] Dollars ($[**]);

5.2.3 First Commercial Sale of a Product in any country or territory outside the United States after receipt of all requisite Regulatory Approvals in such country, [**] Dollars ($[**]);

5.2.4 First Commercial Sale of a Product in any three (3) countries comprising the Major Markets, [**] Dollars ($[**]);

5.2.5 First Commercial Sale of a Product in the United States using an intranasal delivery device other than a unit dose delivery device (a "**Follow-On Product**"), [**] Dollars ($[**]);

5.2.6 First Commercial Sale of a Follow-On Product in the United States, provided, that (i) a Product using a unit dose delivery device in the United States ("**First Product**") has received Regulatory Approval, and the use of the Follow-On Product has an improved naloxone bioavailability profile relative to the First Product and (ii) Patents covering or claiming the Follow-On Product are listed in the FDA's Approved Drug Products with Therapeutic Equivalent Evaluations (or successor thereto) with respect to such Follow-On Product, [**] Dollars ($[**]);

Each milestone payment in this Section 5.2 shall be payable only upon the first achievement of such milestone and no amounts shall be due for subsequent or repeated achievements of such milestone, whether for the same or a different Product. The maximum aggregate amount payable by Adapt pursuant to this Section 5.2 is Seven Million Five Hundred Thousand Dollars ($7,500,000).

5.3 **Sales-Based Milestones.**

5.3.1 In partial consideration of the license rights granted by Lightlake to Adapt hereunder, in the event that the aggregate of all Net Sales in a given Calendar Year exceeds a threshold (each, an "**Annual Net Sales Milestone Threshold**") set forth in the left-hand column of the table immediately below for such Calendar Year (the "**Annual Net Sales-Based Milestone Table**"), Adapt shall pay to Lightlake a milestone payment (each, an "**Annual Net Sales-Based Milestone Payment**") in the corresponding amount set forth in the right-hand column of the Annual Net Sales-Based Milestone Table. In the event that in a given Calendar Year more than one Annual Net Sales Milestone Threshold is exceeded, Adapt shall pay to Lightlake a separate Annual Net Sales-Based Milestone Payment with respect to each Annual Net Sales Milestone Threshold that is exceeded in such Calendar Year. Each such milestone payment shall be due within sixty (60) days after the end of the Calendar Quarter in such Calendar Year in which such milestone was achieved (each, an "**Annual Net Sales-Based Milestone Payment Date**").

Threshold Annual Net Sales Levels	Payment Amount
Thirty Million Dollars ($30,000,000)	Two Million Dollars ($2,000,000)
Forty Million Dollars ($40,000,000)	Six Million Dollars ($6,000,000)
Fifty-Five Million Dollars ($55,000,000)	Ten Million Dollars ($10,000,000)
Seventy-Five Million Dollars ($75,000,000)	Fifteen Million Dollars ($15,000,000)

Two Hundred Million Dollars ($200,000,000)	Fifteen Million Dollars ($15,000,000)

5.3.2 Notwithstanding anything contained in Section 5.3.1, each milestone payment in this Section 5.3 shall be payable only upon the first achievement of such milestone in a given Calendar Year, and no amounts shall be due for subsequent or repeated achievements of such milestone in subsequent Calendar Years. The maximum aggregate amount payable by Adapt pursuant to this Section 5.3 is Forty-Eight Million Dollars ($48,000,000).

5.4 Royalties.

5.4.1 Royalty Rates. As further consideration for the rights granted to Adapt hereunder, subject to Section 5.4.2, commencing upon the First Commercial Sale, Adapt shall pay to Lightlake a royalty on Net Sales during each Calendar Year at the following rates:

Net Sales of all Products	Royalty Rate
Subject to Section 5.4.2, for that portion of aggregate Net Sales during a Calendar Year less than Fifty Million Dollars ($50,000,000).	6%
For that portion of aggregate Net Sales during a Calendar Year equal to or greater than Fifty Million Dollars ($50,000,000) but less than Seventy-Five Million Dollars ($75,000,000).	7.5%
For that portion of aggregate Net Sales during a Calendar Year equal to or greater than Seventy-Five Million Dollars ($75,000,000) but less than One Hundred Million Dollars ($100,000,000).	9%
For that portion of aggregate Net Sales during a Calendar Year equal to or greater than One Hundred Million Dollars ($100,000,000) but less than Two Hundred Million Dollars ($200,000,000).	10%
For that portion of aggregate Net Sales during a Calendar Year equal to or greater than Two Hundred Million Dollars ($200,000,000).	12%

5.4.2 Royalty on Certain Pre-Approval Net Sales. As further consideration for the rights granted to Adapt hereunder, Adapt shall pay to Lightlake a royalty of sixteen percent (16%) of Net Sales of the First Product to the First Responder Market that are made prior to the First Commercial Sale and prior to Regulatory Approval of the First Product, up to aggregate Net Sales of Three Million One Hundred Twenty-Five Thousand Dollars ($3,125,000) (i.e., the maximum royalty payable pursuant to this Section 5.4.2 shall equal $500,000). If royalties are paid under this Section 5.4.2 in the Calendar Year of or before the First Product receives Regulatory Approval, then the initial royalties contemplated by Section 5.4.1 shall be payable only for that portion of aggregate Net Sales during such Calendar Year that exceeds such Net Sales to the First Responder Market.

5.4.3 Generic Reduction. Notwithstanding anything to the contrary in Section 5.4.1, in the event that in any country during a Calendar Quarter there is Generic Competition, the royalties payable to Lightlake for the Net Sales of such Product in such country shall be reduced to [**] ([**]%) percent for such Calendar Quarter. "**Generic Competition**" means, either (i) on a country-by-country and Product-by-Product (with different strengths or presentations of Products being regarded as separate Products for purposes hereof) basis, the unit volume of a Product sold in a country in any Calendar Quarter is less than [**] percent ([**]%) of the unit volume of such Product sold in such country in the last full Calendar Quarter immediately preceding the date on which a Generic Product in respect of such Product was first launched in such country or (ii) on a country-by-country and Product-by-Product (with different strengths of Products being regarded as separate Products for purposes hereof) basis, in the event that there is an authorized generic version of a Product sold by Adapt or its Affiliate or Commercial Sublicensee in a country, the aggregate Net Sales of such Product and such authorized generic version of such Product in any Calendar Quarter are less than [**] percent ([**]%) of the aggregate Net Sales thereof in the last full Calendar Quarter immediately preceding the date on which a Generic Product in respect of such Product was first launched in such country.

5.5 Third Party Royalties. If, during the Term, Adapt elects, in its sole discretion, to seek a license under any Patent of a Third Party that (i) Adapt reasonably determines would be infringed by the Exploitation, in any part of the Territory, of any Product then under Development or being Commercialized by Adapt, its Affiliates or its Sublicensees, or that Adapt determines could be listed in the FDA's Orange Book in respect of one or more Products (including Products in Development), or that claims an invention that Adapt determines could facilitate the Development of one or more new Product(s) (any of the foregoing, "**Core IP**") or (ii) that Adapt otherwise determines is necessary or desirable for Adapt, its Affiliates or Sublicensees to Exploit the Products, then, in either case, Adapt shall be solely responsible for the negotiation and execution of the corresponding license agreement. Any amounts due under any such Third Party license agreement will be borne by Adapt; provided, however, that Adapt shall be entitled to deduct up to fifty percent (50%) of the upfront payment, milestones or royalties paid to such Third Party (on account of rights relating to Products) from the Regulatory Milestones payable by Adapt pursuant to Section 5.2, the Sales-Based Milestones payable by Adapt pursuant to Section 5.3 and the royalties payable by Adapt pursuant to Section 5.4. To the extent that, in any Calendar Quarter with respect to a royalty payment or with respect to milestone payment in the event of a milestone, Adapt was not able to deduct the entire amount of the above percentage of any and all amounts paid to such Third Party in such Calendar Quarter or from such regulatory or sales-based milestone payment, Adapt shall be entitled to carry forward such remaining amounts and deduct them from the royalties due in subsequent Calendar Quarters or a subsequent regulatory or sales-based milestone payment; provided that in no event shall reductions pursuant to this Section 5.5 result in royalties on Product of less than (x) [**] percent ([**]%) of Net Sales in any Calendar Quarter in the case of reductions associated with Core IP or (y) [**] percent ([**]%) of Net Sales in any Calendar Quarter in the case of reductions associated with any other license contemplated by this Section 5.5.

5.6 Royalty Payments and Reports. Adapt shall calculate all amounts payable to Lightlake pursuant to Section 5.4 at the end of each Calendar Quarter, which amounts shall be converted to Dollars, in accordance with Section 5.7. Adapt shall pay to Lightlake the royalty amounts due with respect to a given Calendar Quarter within forty-five (45) days after the end of such Calendar Quarter. Each payment of royalties due to Lightlake shall be accompanied by a statement of the amount of gross sales and Net Sales of each Product in each country during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter.

5.7 Mode of Payment; Offsets. All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, the simple average of prior month-end Exchange Rate and current month-end Exchange Rate based on 9:00 AM Central Time Bloomberg screen on the penultimate Business Day of the corresponding month. The "Exchange Rate" means, with respect to a Business Day, the spot bid rate for X currencies and spot ask rate for non-X currencies for the conversion of the applicable country's or other jurisdiction's currency to Dollars as reported at 9:00 AM Central Time Bloomberg screen on the penultimate Business Day. Adapt shall not have the right to offset, set off or deduct any amounts from or against the amounts due to Lightlake hereunder any amounts owing by Lightlake to Adapt hereunder.

5.8 **Taxes**. The milestones and royalties payable by Adapt to Lightlake pursuant to this Agreement (each, a "**Payment**") shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Where any sum due to be paid to either Party hereunder is subject to any withholding or similar tax, the Parties shall use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the payor shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to payee and secure and send to payee the best available evidence of such payment.

5.9 **Interest on Late Payments**. If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of three percent above LIBOR, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

5.10 **Funding under the Initial Development Plan**. In consideration for Lightlake's performance of its obligations under the Initial Development Plan, upon the terms and conditions contained herein, for the shorter of the Term or the first (12) months after the Effective Date, Adapt shall pay to Lightlake [**] Dollars ($[**]) per month plus the reasonable and documented out-of-pocket costs and expenses incurred by Lightlake in delivering reasonably requested transition support in accordance with the Initial Development Plan payable no later than fifteen days after the start of each such month and with respect to out-of-pocket expenses, payable no later than thirty days after the receipt of an invoice from Lightlake. Payments made under this Section 5.10 shall not be considered Development Costs, Regulatory Costs or Commercialization Costs for purposes of Section 3.8.

5.11 **Development Costs; Regulatory Costs and Commercialization Costs.**

5.11.1 **Report of Development Costs, Regulatory Costs and Commercialization Costs**. Within thirty (30) days following the end of each calendar month beginning with the Effective Date and ending with the month in which the Lightlake Cost Cap has been reached, Lightlake shall prepare and deliver to Adapt a report detailing its Development Costs for the preceding month, and Adapt shall, within fifteen (15) days thereafter, prepare and deliver to Lightlake a report (i) detailing Adapt's Development Costs, Regulatory Costs and Commercialization Costs incurred during such preceding month,(ii) setting forth a reconciliation of the amounts for which each Party is responsible pursuant to Section 3.8.1, and (iii) indicating the amount in Dollars due to Lightlake or Adapt, as applicable for such calendar month (each, a **"Reconciliation Development Payment"**). Each Party shall provide such additional detail regarding its reported costs as the other Party shall reasonably request.

5.11.2 **Reconciliation Payments**. Within fifteen (15) days after Adapt delivers each of its monthly reports pursuant to Section 5.11.1, the Party to whom a Reconciliation Development Payment is due shall issue an invoice to the other Party for the Reconciliation Development Payment, which invoice shall be due and payable within fifteen (15) days thereafter.

5.12 **Financial Records**. Adapt shall, and shall cause its Affiliates to, keep complete and accurate books and records pertaining to Net Sales of Products, and any other records reasonably required to be maintained with respect to each Party's obligations under this Agreement, and each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of all Development Costs, Regulatory Costs and Commercialization Costs invoiced by one Party to the other Party pursuant to Section 5.11.2 in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by a Party and its Affiliates until the later of (i) three (3) years after the end of the period to which such books and records pertain, and (ii) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

5.13 **Audit.**

5.13.1 **Audit**. At the request of a Party, the other Party shall, and shall cause its Affiliates to, permit an independent auditor designated by auditing Party and reasonably acceptable to the audited Party, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 5.12 to ensure the accuracy of all reports and payments made hereunder; provided, however, that such audit right may be exercised no more than once in any Calendar Year; provided, that once the reports and payments for any particular period have been audited hereunder, such reports and payments shall not be the subject of any future audit absent fraud; provided, further, that the reports and payments made in any particular Calendar Year shall be subject to audit only until the end of the third Calendar Year following the Calendar Year in which such reports or payments were made. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a discrepancy in favor of the audited Party of more than five percent (5%) from the reported amounts for the audited Party, in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 5.13.2, if such audit concludes that (x) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 5.9, or (y) excess payments were made by audited Party, the auditing Party shall reimburse such excess payments, in either case ((x) or (y)), within sixty (60) days after the date on which such audit is completed by the auditing Party. The audited Party may require the accounting firm to sign a customary non-disclosure agreement before providing the accounting firm access to the audited Party's facilities or records. Upon completion of the audit, the accounting firm shall provide both Parties a written report disclosing whether the reports submitted by the audited Party are correct or incorrect, whether the calculations set forth in the reports submitted by the audited Party are correct or incorrect, and, in each case, the specific details concerning any discrepancies. No other information shall be provided to the auditing Party.

5.13.2 **Audit Dispute**. In the event of a dispute with respect to any audit under Section 5.13.1, Lightlake and Adapt shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Audit Arbitrator**"). The decision of the Audit Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in inverse proportion to Party's positions with respect to such dispute, as determined by the Audit Arbitrator. Not later than ten (10) days after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 5.9, or the auditing Party shall reimburse the excess payments, as applicable.

5.13.3 **Confidentiality**. The auditing Party shall treat all information subject to review under this Section 5.13 in accordance with the confidentiality provisions of Article 7 and the Parties shall cause the Audit Arbitrator to enter into a reasonably acceptable confidentiality agreement with the auditing Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

5.14 **No Other Compensation**. Each Party hereby agrees that the terms of this Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one Party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, independent contractors or agents, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

ARTICLE VI

INTELLECTUAL PROPERTY

6.1 Ownership of Intellectual Property.

6.1.1 Ownership of Technology. As between the Parties, each Party shall own and retain all right, title, and interest in and to any and all Inventions and Information that are conceived, discovered, developed, or otherwise made solely by or on behalf of such Party (or its Affiliates or Sublicensees) under or in connection with this Agreement, whether or not patented or patentable, and any and all Patents and other intellectual property rights with respect thereto.

6.1.2 Ownership of Joint Patents and Joint Know-How. As between the Parties, the Parties shall each own an equal, undivided interest in any and all (i) Inventions and Information that are conceived, discovered, developed or otherwise made jointly by or on behalf of Lightlake or its Affiliates, on the one hand, and Adapt or its Affiliates or Sublicensees, on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable (the "**Joint Know-How**"), and (ii) Patents (the "**Joint Patents**") and other intellectual property rights with respect to the Inventions and Information described in clause (i) (together with Joint Know-How and Joint Patents, the "**Joint Intellectual Property Rights**"). Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates, (and in the case of Adapt, its Sublicensees) to so disclose, the development, making, conception or reduction to practice of any Joint Know-How or Joint Patents. Subject to the licenses and rights of reference granted under Sections 4.1 and 4.2, and each Party's exclusivity obligations in Section 4.5, each Party shall have the right to Exploit the Joint Intellectual Property Rights without a duty of seeking consent or accounting to the other Party.

6.1.3 United States Law. The determination of whether Information and Inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where such conception, discovery, development or making occurs.

6.1.4 Assignment Obligation. Each Party shall cause all Persons who perform activities for such Party under this Agreement to be under an obligation to assign their rights in any Inventions resulting therefrom to such Party.

6.2 Maintenance and Prosecution of Lightlake Patents.

6.2.1 Lightlake Right. As between the Parties, Lightlake shall have the first right, but not the obligation, to prepare, file, prosecute (including any reissues, re-examinations, post-grant proceedings, requests for patent term extensions, supplementary protection certificates, interferences, derivation proceedings, supplemental examinations and defense of oppositions) and maintain the Lightlake Patents. Lightlake shall keep Adapt informed with regard to the filing, prosecution and maintenance of Lightlake Patents, including by providing Adapt with (i) copies of material communications to and from any patent authorities regarding Lightlake Patents, and (ii) drafts of any material filings or responses to be made to such patent authorities regarding Lightlake Patents sufficiently in advance of submitting such filings or responses so as to allow a reasonable opportunity for Adapt to review and comment thereon. Lightlake shall not be bound by, but shall consider in good faith, the comments of Adapt with respect to such Lightlake drafts and with respect to strategies for filing and prosecuting the Lightlake Patents. If Adapt fails to provide its comments with respect to such filing and prosecution of Lightlake Patents reasonably in advance of the deadline for filing or otherwise responding to the patent authorities, Lightlake shall be free to act without consideration of Adapt's comments.

6.2.2 Adapt Right. In the event that Lightlake intends not to prepare, file, prosecute, or maintain a Lightlake Patent, Lightlake shall provide reasonable prior written notice to Adapt of such intention (which notice shall, in any event, be given no later than ten (10) days prior to the next deadline for any action that may be taken with respect to such Patent), and Adapt shall thereupon have the option, in its sole discretion and at its sole cost, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Patent on Lightlake's behalf with respect to claims covering Products.

6.2.3 Costs. Subject to Section 6.2.2, the costs of prosecution and maintenance of the Lightlake Patents shall be initially borne by the Party conducting such prosecution and maintenance.

6.3 Maintenance and Prosecution of Product Specific Patents, Adapt Applied Patents and Joint Patents.

6.3.1 Adapt Right. Adapt shall have the first right, but not the obligation, to prepare, file, prosecute (including any reissues, re-examinations, post-grant proceedings, requests for patent term extensions, supplementary protection certificates, interferences, derivation proceedings, supplemental examinations and defense of oppositions) and maintain the Adapt Applied Patents, the Product Specific Patents and Joint Patents worldwide, at Adapt's cost. Adapt shall keep Lightlake informed with regard to the filing, prosecution and maintenance of Adapt Applied Patents, Product Specific Patents and Joint Patents, including by providing Lightlake with (i) copies of material communications to and from any patent authorities regarding Adapt Applied Patents, the Product Specific Patents and Joint Patents, and (ii) drafts of any material filings or responses to be made to such patent authorities regarding Adapt Applied Patents and Joint Patents sufficiently in advance of submitting such filings or responses so as to allow a reasonable opportunity for Lightlake to review and comment thereon. Adapt shall not be bound by, but shall consider in good faith, the comments of Lightlake with respect to such Adapt drafts and with respect to strategies for filing and prosecuting the Adapt Applied Patents, the Product Specific Patents and the Joint Patents. If Lightlake fails to provide its comments with respect to such filing and prosecution of Adapt Applied Patents, Product Specific Patents or Joint Patents reasonably in advance of the deadline for filing or otherwise responding to the patent authorities, Adapt shall be free to act without consideration of Lightlake's comments.

6.3.2 Lightlake Right. In the event that Adapt intends not to prosecute or maintain a Adapt Applied Patent, Product Specific Patent or a Joint Patent in any country in the world, Adapt shall provide reasonable prior written notice to Lightlake of such intention (which notice shall, in any event, be given no later than ten (10) days prior to the next deadline for any action that may be taken with respect to such Adapt Applied Patent or Joint Patent), and Lightlake shall thereupon have the option, in its sole discretion and at its sole cost, to assume the control and direction of the prosecution and maintenance of such Adapt Applied Patent, Product Specific Patent or Joint Patent in such country on Adapt's behalf.

6.3.3 Costs. Subject to Section 6.3.2, the costs of prosecution and maintenance of the Adapt Applied Patent, Product Specific Patent or a Joint Patent shall be borne by the Party conducting such prosecution and maintenance.

6.4 Infringement by Third Parties.

6.4.1 Notice. Each Party shall promptly give the other written notice if it reasonably believes that any Lightlake Patent, Lightlake Know-How, Adapt Applied Patent, Adapt Applied Know-How, Product Specific Patent, Joint Invention or Joint Patent is being infringed or misappropriated by a Third Party, and shall provide the other Party with all available evidence supporting such belief.

6.4.2 Products. In the event of an actual or suspected infringement or misappropriation of any Lightlake Patent, Lightlake Know-How, Adapt Applied Patent, Adapt Applied Know-How, Product Specific Patent, Joint Invention or Joint Patent by a Third Party that is conducting the manufacture, use, sale, offer for sale or import of a Product or a product which may compete with a Product, the following shall apply:

(a) The Party first becoming aware of such actual or suspected infringement shall promptly notify the other Party. Adapt shall have the first right, but not the obligation, to institute and prosecute an action or proceeding to abate such infringement or misappropriation and to resolve such matter by settlement or otherwise.

(b) Adapt agrees to notify Lightlake of its intention to bring an action or proceeding and to keep Lightlake informed of material developments in the prosecution or settlement of such action or proceeding. Adapt shall be responsible for all costs and expenses of any action or proceeding that Adapt initiates and maintains. Subject to Section 6.4.3(a), Lightlake shall cooperate fully in any such action or proceeding at its expense by executing and making available such documents as Adapt may reasonably request. Lightlake may be represented by counsel of its choice in any such action or proceeding, at Lightlake's expense, acting in an advisory but not controlling capacity. Subject to Section 6.4.3, the prosecution, settlement, or abandonment of any infringement action or proceeding brought by Adapt shall be at Adapt's sole discretion.

(c) If Adapt fails or elects not to exercise such first right within sixty (60) days of evidence of an actual infringement, Lightlake shall have the right, at its discretion, to institute and prosecute an action or proceeding to abate such infringement and to resolve such matter by settlement or otherwise. Lightlake shall keep Adapt informed of material developments in the prosecution or settlement of such action or proceeding. Lightlake shall be responsible for all costs and expenses of any action or proceeding that Lightlake initiates. Adapt shall cooperate fully by joining as a party plaintiff if required to do so by law to maintain such action and by executing and making available such documents as Lightlake may reasonably request. Adapt may be represented by counsel in any such action or proceeding at its own expense. The prosecution, settlement, or abandonment of any infringement action or proceeding brought by Lightlake shall be at Lightlake's sole discretion; provided, that Lightlake may not enter into any settlement that requires Adapt or its Affiliates or Sublicensees to pay any sum of money, subjects Adapt or its Affiliates or Sublicensees to any injunctive relief or other equitable remedies, or otherwise adversely affects Adapt's rights or interests in the applicable Lightlake Patent, Lightlake Know-How, Adapt Applied Patent, Adapt Applied Know-How, Product Specific Patent, Joint Invention or Joint Patent or with respect to a Product without Adapt's written consent, which consent shall not be unreasonably withheld.

6.4.3 Cooperation; Damages.

(a) If one Party brings any suit, action or proceeding under Section 6.4.2, the other Party agrees to be joined as party plaintiff if necessary to prosecute the suit, action or proceeding and to give the first Party reasonable authority to file and prosecute the suit, action or proceeding at the first Party's cost; provided, however, that neither Party will be required to transfer any right, title or interest in or to any property to the other Party or any other party to confer standing on a Party hereunder.

(b) The Party not pursuing the suit, action or proceeding hereunder will provide reasonable assistance to the other Party, including by providing access to relevant documents and other evidence and making its employees available, subject to the other Party's reimbursement of any out-of-pocket costs and expenses incurred by the non-enforcing or defending Party in providing such assistance.

(c) Adapt shall not, without the prior written consent of Lightlake (in its sole discretion), enter into any compromise or settlement relating to any claim, suit or action that it brought under Section 6.4.2 involving a Lightlake Patent that admits the invalidity or unenforceability of such Lightlake Patent or requires Lightlake to pay any sum of money, or otherwise adversely affects the rights of Lightlake with respect to such Lightlake Patents or Lightlake's rights hereunder (including the rights to receive payments).

(d) Any settlements, damages or other monetary awards (a "**Recovery**") recovered pursuant to a suit, action or proceeding brought pursuant to Section 6.4.2 will be allocated first to the costs and expenses of the Party taking such action, and second, to the costs and expenses (if any) of the other Party, with any remaining amounts (if any) to be allocated as follows: (i) to the extent that such Recovery is a payment for lost sales of Product, any remaining amount will be paid to Adapt but will be considered Net Sales for such Product during the Calendar Quarter in which such amounts are received solely for the purposes of calculating royalties pursuant to Section 5.4 and (ii) in the event such Recovery relates to the Product generally, all remaining amounts shall be payable to the Party taking such action.

6.4.4 Other Infringement and Defense of Lightlake Patents. For clarity, with respect to any and all infringement or defense of any Lightlake Patent with respect to products other than Products, subject to Section 6.6, Lightlake (or its designee) shall have the sole and exclusive right to bring an appropriate suit or other action against any Person engaged in such infringement or defense of any such Lightlake Patents in its sole discretion and Adapt shall have no rights with respect thereto.

6.5 Patent Listings. Adapt shall have the sole right to make all filings with Regulatory Authorities with respect to Product Specific Patents, Adapt Applied Patents and Lightlake Patents (subject to Section 6.6) and Joint Patents in relation to the Product, including as required or allowed (i) in the United States, in the FDA's Orange Book, and (ii)outside the United States, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents; provided that Adapt shall consult with Lightlake prior to making any such filing and consider Lightlake's comments on such filing in good faith.

6.6 Coordination In Respect of Lightlake Patents. Notwithstanding anything herein, in the event that a Party reasonably believes, in its sole discretion, that there is a risk that any enforcement action or proceeding in respect of any Lightlake Patent, or any listing of a Lightlake Patent in the FDA's Orange Book, in respect of a Product or any other product, would restrict the scope, or adversely affect the enforceability or validity, of such Lightlake Patent in relation to such Party's rights in such Lightlake Patent, no listing, suit, action, proceeding or strategic decision (including decisions concerning jurisdiction, venue, joinder, causes of action (including patent infringement claims and enforcement actions), claims, defenses, substantive motions, claim construction, tutorials, experts, covenants-not-to-sue, dismissal, settlement, trial and/or appeal) may be made by the Party controlling (or having the right to control) such action or proceeding or listing without first notifying the other Party of such intended action, consulting in good faith with the other Party with respect thereto and reasonably considering the other Party's views with respect to such action and, in the case of Adapt, its Affiliates and Sublicensees, without the prior written consent of Lightlake, which consent shall not be unreasonably withheld, conditioned, or delayed.

6.7 **Patent Marking**. Adapt shall mark the Product marketed and sold by Adapt (or its Affiliate or distributor) hereunder with appropriate patent numbers or indicia at Lightlake's request.

ARTICLE VII
CONFIDENTIALITY AND NON-DISCLOSURE

7.1 **Confidentiality Obligations**. At all times during the Term and for a period of ten (10) years following termination or expiration hereof in its entirety, each Party shall, and shall cause its Affiliates, and its and their respective officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is reasonably necessary or useful for the performance of a Party's obligations, or the exercise of a Party's rights, under this Agreement. Confidential Information disclosed under the Existing CDAs shall be considered Confidential Information disclosed under this Agreement and subject to the terms and conditions of this Agreement. Notwithstanding the foregoing, but to the extent the receiving Party can demonstrate by documentation or other competent proof, the confidentiality and non-use obligations under this Section 7.1 with respect to any Confidential Information shall not include any information that:

7.1.1 has been published by a Third Party or is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

7.1.2 has been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information; *provided* that the foregoing exception shall not apply with respect to Joint Know-How;

7.1.3 is subsequently received by the receiving Party from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party; or

7.1.4 has been independently developed by or for the receiving Party without reference to, or use or disclosure of the disclosing Party's Confidential Information; *provided* that the foregoing exception shall not apply with respect to Joint Know-How.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party. Joint Know-How shall be considered the Confidential Information of both Parties.

7.2 **Permitted Disclosures**. Each Party may disclose Confidential Information to the extent that such disclosure is:

7.2.1 in the reasonable opinion of the receiving Party's legal counsel, required to be disclosed pursuant to Applicable Law or made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction, including by reason of filing with securities regulators; provided, however, that the receiving Party, to the extent practicable and legally permissible, shall first have given prompt written notice (and to the extent practicable and legally permissible, at least five (5) Business Days' notice) to the disclosing Party and given the disclosing Party a reasonable opportunity to take whatever action it deems necessary to protect its Confidential Information (for example, quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or regulatory body or, if disclosed, be used only for the purposes for which the order was issued). In the event that no protective order or other remedy is sought or obtained, or the disclosing Party waives compliance with the terms of this Agreement, receiving Party shall furnish only that portion of Confidential Information which receiving Party is advised by counsel is legally required to be disclosed;

7.2.2 made by or on behalf of the receiving Party to Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval in accordance with the terms of this Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

7.2.3 made to its (actual or potential) Sublicensees, other Persons who have been granted rights to Exploit Products in accordance with this Agreement, acquirers, financing sources, investors or permitted assignees under Section 11.3 and to their financial and legal advisors who have a need to know such Confidential Information in connection with any such sublicense, financing, investment, acquisition or assignment; provided that any such recipient of such Confidential Information agrees to be bound by the confidentiality and non-use restrictions contemplated hereby; provided, further that the Party making such disclosure shall remain responsible for any failure by any such Person to treat such Confidential Information as required under this Article 7.

7.2.4 made to its or its Affiliates' financial and legal advisors who have a need to know such Confidential Information, and in the case of Lightlake, any Person who holds or will hold in the future any interest in any of Lightlake's products, and, in each case, are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use, in each case, at least as restrictive as those set forth in this Agreement; provided that the receiving Party shall remain responsible for any failure by such financial and legal advisors and other Persons contemplated by this Section 7.2.4, to treat such Confidential Information as required under this Article 7.

7.3 **Use of Name**. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 7.3 shall not prohibit either Party from making any disclosure identifying the other Party that are permitted pursuant to Section 7.2 or Section 7.4.

7.4 **Public Announcements**. The Parties have agreed upon the content of press releases which shall be issued substantially in the form attached hereto as Schedule 7.4, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Except as contemplated by Section 7.5 or as otherwise agreed by the Parties, neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed or for information which has previously been made public. In the event a Party is, in the opinion of its counsel, required by Applicable Law

or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than three (3) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon and such required Party shall consider all comments from such other Party in good faith.

7.5 Publications. Each Party recognizes that the publication of papers regarding results of and other information regarding activities under this Agreement may be beneficial to the Development and Commercialization of Products. Accordingly, Adapt and its Affiliates and Sublicensees shall have the right to publish or present or permit the publication or presenting of papers and presentations that contain clinical data regarding, or pertain to results of clinical testing of, Products (each, a "**Publication**"); provided, however, that such publications do not contain the Confidential Information of Lightlake and Lightlake shall be provided with a copy of any such Publication in advance of public publication or presentation thereof and Adapt shall consider in good faith any comments Lightlake may have with respect thereto. For clarity, Lightlake Confidential Information shall include all Lightlake Information existing on the Effective Date other than the Pharmacokinetics Data.

7.6 Return of Confidential Information. Upon the effective date of the termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information to which such first Party does not retain rights under the surviving provisions of this Agreement: (i) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (ii) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; *provided, however*, the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

7.7 Survival. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 7.1.

ARTICLE VIII
REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Lightlake and Adapt each represents and warrants to the other, as of the Effective Date, and covenants, as follows:

8.1.1 Organization. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

8.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of its obligations contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (i)such Party's charter documents, bylaws, or other organizational documents, (ii)in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound, (iii)any requirement of any Applicable Law, or (iv) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.

8.1.3 Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

8.1.4 Consents and Approvals. No consent, approval, waiver, order or authorization of, or registration, declaration or filing with, any Third Party is required in connection with the execution, delivery and performance of this Agreement by such Party or the performance by such Party of its obligations contemplated hereby or thereby.

8.1.5 No Inconsistent Obligation. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

8.2 Additional Representations and Warranties of Lightlake. Lightlake further represents and warrants to Adapt, as of the Effective Date, and covenants, as follows:

8.2.1 Lightlake has the right to grant the licenses specified herein.

8.2.2 Lightlake is the sole and exclusive owner of the entire right, title and interest in the Product Specific Patents and the Lightlake Know-How. Such rights are not subject to any Liens in favor of, or claims of ownership by, any Third Party. True and correct copies of the complete file wrapper and other documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of the Product Specific Patents, as amended through the date hereof, have been provided to Adapt prior to the date first above written. No Lightlake Patents exist as of the date hereof.

8.2.3 The Product Specific Patents are being diligently prosecuted in each country in respect of which applications have been made in the respective patent offices in accordance with all Applicable Laws and regulations. The Product Specific Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.

8.2.4 To Lightlake's knowledge, the Exploitation by Adapt and its Affiliates and Sublicensees hereunder of the Products will not infringe any Patent or other intellectual property or proprietary right of any Person.

8.2.5 The conception, development and reduction to practice of the Product Specific Patents and Lightlake Know-How existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person. There are no claims, judgments or settlements against or amounts with respect thereto owed by Lightlake or any of its Affiliates relating to the existing Regulatory Filings, the Product Specific Patents or the Lightlake Know-How.

8.2.6 Lightlake Controls all Information, other than Identifiable Private Information (as defined in the NIDA Agreement), generated in relation to the Development activities contemplated by the NIDA Agreement.

8.2.7 To its knowledge, Lightlake has conducted, and its contractors and consultants have conducted, all Development with respect to the Product that it has conducted prior to the Effective Date in accordance with good laboratory practice and good clinical practices, as applicable and defined by the FDA, and Applicable Law.

8.2.8 Neither Lightlake nor any of its Affiliates, nor any of its or its Affiliates' directors or officers has been debarred or is subject to debarment and neither Lightlake nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section. Lightlake shall inform Licensee in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Lightlake's knowledge, is threatened, relating to the debarment or conviction of Lightlake or any Person performing services on behalf of Lightlake hereunder.

8.2.9 To Lightlake's knowledge, no Person is infringing or threatening to infringe the Product Specific Patents or misappropriating or threatening to misappropriate the Lightlake Know-How.

8.2.10 Schedule 8.2.10 hereto includes a list of all agreements with Third Parties related to the Products, including agreements related to the Development and Manufacture of the Products, in each case, that are in effect as of the Effective Date or that have post-termination obligations (other than solely obligations to keep information confidential or to restrict use thereof after termination) for Lightlake or the Third Party that are in effect as of the Effective Date (collectively, the "Relevant Contracts"). Lightlake has disclosed and made available to Adapt full and complete copies of all such Relevant Contracts to Adapt. Lightlake represents and warrants to Adapt that each Relevant Contract is a legal, valid, binding and enforceable agreement of Lightlake or one of its Affiliates, as applicable, and is in full force and effect, and neither Lightlake nor any of its Affiliates or, any other party thereto is in default or breach under the terms of, or has provided any notice of any intention to terminate or modify, any such Relevant Contract, and, no event or circumstance has occurred that, with notice or lapse of time or both, would constitute a breach thereof or a default thereunder or would result in a termination, modification, acceleration or vesting of any rights or obligations or loss of benefits thereunder.

8.2.11 Lightlake has made available to Adapt all material Regulatory Documentation owned or possessed by Lightlake regarding or related to the Products. Lightlake has prepared, maintained or retained all material Regulatory Documentation required to be maintained or reported pursuant to and in accordance with the applicable requirements of good laboratory practices and good clinical practices, as applicable, as defined by the FDA, to the extent required, and Applicable Law, and such Regulatory Documentation does not contain any materially false or misleading statements.

8.2.12 Lightlake has disclosed to Adapt all material information known to Lightlake and its Affiliates with respect to the Products, including with respect to the safety and efficacy thereof.

8.3 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE IX
INDEMNITY

9.1 Indemnification of Lightlake. Adapt shall indemnify Lightlake, its Affiliates and its and their respective directors, officers, employees, and agents ("**Lightlake Indemnitees**"), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs, and expenses (including attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "**Third Party Claims**") incurred by or rendered against the Lightlake Indemnitees arising from or occurring as a result of: (i) the breach by Adapt of this Agreement, (ii) the gross negligence or willful misconduct on the part of Adapt or its Affiliates or Sublicensees or its or their distributors or contractors or its or their respective directors, officers, employees, and agents in performing its or their obligations under this Agreement, (iii) the Exploitation by Adapt or any of its Affiliates or Sublicensees or its or their distributors or contractors of any Product, or (iv) the breach of an Assigned Agreement by any of Adapt or its Affiliates or Sublicensees or subcontractors or any of their successors or assigns after the Effective Date, except (in each case) to the extent Lightlake has an obligation to indemnify Adapt Indemnities pursuant to Section 9.2 for such Losses and Third Party Claims.

9.2 Indemnification of Adapt. Lightlake shall indemnify Adapt, its Affiliates and its and their respective directors, officers, employees, and agents (the "**Adapt Indemnitees**"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims incurred by or rendered against the Adapt Indemnitees arising from or occurring as a result of: (i) the breach by Lightlake of this Agreement, (ii) the gross negligence or willful misconduct on the part of Lightlake or its Affiliates or its or their respective directors, officers, employees, and agents in performing its obligations under this Agreement, (iii) any claim by any current or former Lightlake shareholder, investor or contributor that any Adapt Indemnitee or any Sublicensee owes such Person any compensation in relation to the Exploitation of the Products or the rights granted hereunder, (iv) the pharmacokinetics study ongoing as of the Effective Date in respect of a Product, or (v) Lightlake's or its Affiliate's or subcontractor's violation of any Applicable Law, breach of any Relevant Contract, or gross negligence or willful misconduct, in relation to the Exploitation of Products prior to the Effective Date, except (in each case) to the extent Adapt has an obligation to indemnify Lightlake Indemnities pursuant to Section 9.1 for such Losses and Third Party Claims.

9.3 Notice of Claim. All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 9, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

9.4 Control of Defense.

9.4.1 In General. Except as otherwise contemplated by Article 6, at its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the

indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 9.4.2, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

9.4.2 Right to Participate in Defense. Without limiting Section 9.4.1, any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided, however*, that such employment shall be at the Indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing, (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.4.1 (in which case the Indemnified Party shall control the defense), or (iii) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law or ethical rules.

9.4.3 Settlement. Except as otherwise contemplated by Article 6, with respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.4.1, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided* it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party, not to be unreasonably withheld, conditioned or delayed.

9.4.4 Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

9.4.5 Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

9.5 Special, Indirect, and Other Losses. EXCEPT IN THE EVENT OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 7, AND EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 9, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

9.6 Insurance. Adapt shall maintain insurance, including clinical trials insurance and product liability insurance, which is consistent with normal business practices of similarly situated companies at all times during which the Product is being clinically tested in human subjects or commercially distributed or sold, as applicable, by Adapt pursuant to this Agreement, and the clinical trials insurance coverage shall, prior to the First Commercial Sale of a Product, in no event be less than Five Million Dollars ($5,000,000) per loss occurrence and Five Million Dollars ($5,000,000) in the aggregate, and product liability insurance coverage shall, after such First Commercial Sale, in no event be less than Ten Million Dollars ($10,000,000) per loss occurrence and Ten Million Dollars ($10,000,000) in the aggregate. It is understood that such insurance shall not be construed to create a limit of Adapt's liability with respect to its indemnification obligations under this Article 9. Notwithstanding the foregoing, Adapt shall have no obligation to maintain any insurance covering the pharmacokinetics study ongoing as of the Effective Date in respect of a Product or any liabilities relating thereto.

ARTICLE X
TERM AND TERMINATION

10.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until terminated in accordance with this Article 10 (such period, the "**Term**").

10.2 Adapt Termination for Convenience. Adapt shall have the right to terminate this Agreement in its sole discretion, either in its entirety or in respect of one or more countries, at any time by providing sixty (60) days prior written notice to Lightlake.

10.3 Termination for Material Breach. If either Party (the "**Non-Breaching Party**") believes that the other Party (the "**Breaching Party**") has materially breached one or more of its obligations under this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party specifying the nature of the alleged breach in reasonable detail (a "**Default Notice**"). Thereafter, the Non-Breaching Party shall have the right to terminate this Agreement if the breach asserted in such Default Notice has not been cured within sixty (60) days after such Default Notice. Notwithstanding the foregoing, (i) if such material breach, by its nature, cannot be remedied within such sixty (60) day cure period, but can be remedied over a longer period not expected to exceed one hundred and fifty (150) days, then such sixty (60) day period shall be extended for up to an additional ninety (90) days provided that the Breaching Party provides the Non-Breaching Party with a reasonable written plan for curing such material breach and uses Commercially Reasonable Efforts to cure such material breach in accordance with such written plan and (ii) if such material breach cannot be cured, but the

effects of such material breach are not such that the Non-Breaching Party would be deprived of the material benefits the Non-Breaching Party would reasonably be expected to derive from this Agreement in the absence of such material breach, then the Non-Breaching Party shall not be entitled to terminate this Agreement on the basis of such material breach unless the Breaching Party has previously committed a substantially similar material breach of this Agreement. For clarity, a breach of Section 3.2.3 of this Agreement shall not, notwithstanding anything herein, fall within the exception in subpart (ii) of the immediately preceding sentence.

10.4 Additional Termination by Lightlake for Patent Challenge. In the event that Adapt or any of its Affiliates or Commercial Sublicensees, institutes, prosecutes, or otherwise participates in (or knowingly and intentionally aids any Third Party in instituting, prosecuting, or participating in), at law or in equity or before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action, or cause of action for declaratory relief, damages, or any other remedy, or for an enjoinment, injunction, or any other equitable remedy, including any interference, re-examination, opposition, or any similar proceeding, alleging that any claim in a Lightlake Patent is invalid, unenforceable, or otherwise not patentable or would not be infringed by Adapt's activities absent the rights and licenses granted hereunder, Lightlake shall have the right to terminate this Agreement in its entirety, including the rights of any Sublicensees, upon written notice to Adapt, unless Adapt withdraws or terminates the same, or terminates its agreement with such or Commercial Sublicensee, within ten (10) days after receipt of notice from Lightlake referencing this Section 10.4.

10.5 Termination for Insolvency. In the event that either Party (i) files for protection under bankruptcy or insolvency laws, (ii) makes an assignment for the benefit of creditors, (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing, (iv) proposes a written agreement of composition or extension of its debts, (v) proposes or is a party to any dissolution or liquidation, (vi) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within sixty (60) days of the filing thereof, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

10.6 Effects of Termination. In the event of a termination of this Agreement in its entirety by Lightlake pursuant to Sections 10.3 and 10.4 or by Adapt pursuant to Section 10.2:

10.6.1 all rights and licenses granted by Lightlake hereunder shall immediately terminate;

10.6.2 Adapt shall, and hereby does effective as of the effective date of termination, grant Lightlake an exclusive license, with the right to grant multiple tiers of sublicenses, under the Adapt Applied Patents, Adapt Applied Know-How, and Adapt's rights under the Joint Patents and Joint Know-How to Exploit Products;

10.6.3 Adapt shall, and hereby does, effective as of the effective date of termination, assign to Lightlake at Adapt's expense, all of its right, title, and interest in and to all Regulatory Approvals applicable to any Product, and all Regulatory Documentation specific to such Regulatory Approvals then owned by Adapt or any of its Affiliates, and shall use Commercially Reasonable Efforts to cause any and all Sublicensees to assign to Lightlake any such Regulatory Approvals and related Regulatory Documentation then owned by such Sublicensee;

10.6.4 Adapt shall, and hereby does effective as of the effective date of termination, grant Lightlake an exclusive, license and right of reference, with the right to grant multiple tiers of sublicenses and further rights of reference, under all Regulatory Documentation (including any Regulatory Approvals) then owned or Controlled by Adapt or any of its Affiliates that are not assigned to Lightlake pursuant to Section 10.6.3 above that are necessary or useful for Lightlake or any of its Affiliates or sublicensees to Exploit any Product and any improvement to any of the foregoing, as such Regulatory Documentation exists as of the effective date of such termination of this Agreement and Adapt shall use Commercially Reasonable Efforts to cause its Commercial Sublicensees to grant comparable rights under all Regulatory Documentation (including any Regulatory Approvals) then owned or Controlled by such Commercial Sublicensees;

10.6.5 at Lightlake's request, assign to Lightlake all right, title, and interest of Adapt in each Product Trademark at Adapt's expense; and

10.6.6 at Lightlake's request, assign to Lightlake all right, title, and interest in and to the Development Data that Adapt is not precluded from disclosing or assigning to Lightlake pursuant to the terms of any applicable agreement with a Third Party; provided, however, that Adapt shall use Commercially Reasonable Efforts (which shall not include any obligation to expend money) to obtain the consent of the applicable Third Party for such disclosure and/or assignment in the event that Adapt is so precluded.

10.7 Transition Assistance.

10.7.1 In the event of a termination of this Agreement in its entirety by Lightlake pursuant to Sections 10.3 and 10.4 or by Adapt pursuant to Section 10.2, Adapt shall:

(a) cooperate with Lightlake and notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect the transfer of the Regulatory Documentation set forth in Section 10.6.3;

(b) unless expressly prohibited by any Regulatory Authority, at Lightlake's written request, transfer control to Lightlake of all clinical studies being conducted by Adapt as of the effective date of termination and continue to conduct such clinical studies, at Adapt's cost, for up to six (6) weeks to enable such transfer to be completed without interruption of any such clinical study except if this Agreement is terminated by Adapt pursuant to Section 10.3; in which case such expense shall be borne by Lightlake; provided that (A) Lightlake shall not have any obligation to continue any clinical study unless required by Applicable Law, and (B) with respect to each clinical study for which such transfer is expressly prohibited by the applicable Regulatory Authority, if any, Adapt shall continue to conduct such clinical study to completion, at Adapt's cost; except if this Agreement is terminated by Adapt pursuant to Section 10.3; in which case such cost shall be borne by Lightlake;

(c) at Lightlake's request, assign (or cause its Affiliates to assign) to Lightlake any or all agreements with any Third Party with respect to the conduct of pre-clinical

development activities or clinical studies for the Products, including agreements with contract research organizations, clinical sites, and investigators, unless, with respect to any such agreement, such agreement expressly prohibits such assignment, in which case Adapt shall cooperate with Lightlake in reasonable respects to secure the consent of the applicable Third Party to such assignment; and Lightlake shall assume all ongoing obligations under all such contracts so assigned;

(d) at Lightlake's written request, Adapt shall assign to Lightlake any Third Party contracts for the Manufacture of Products that may be assigned without the counterparty's consent or, in the case of any such contract that cannot be so assigned without consent, Adapt shall use Commercially Reasonable Efforts (which shall not include any obligation to expend money) to obtain any requisite consent for such assignment and shall assign such contract to Lightlake upon receipt of such consent, and, in the case of each such assignment, Lightlake shall assume all of Adapt's obligations under the relevant contract, except to the extent that the same relate to any breach of such contract by Adapt; and

(e) Adapt shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary under, or as Lightlake may reasonably request in connection with, or to carry out more effectively the purpose of, or to better assure and confirm unto Lightlake its rights under, this Section 10.7.1 and Section 10.6.

10.8 Post-Termination Royalties.

10.8.1 As further consideration for the licenses, assignments and transfers set forth in Section 10.6 and Section 10.7, following termination of this Agreement by Lightlake pursuant to Section 10.3 or 10.4 or by Adapt pursuant to Section 10.2, until Adapt has recouped one-hundred percent (100%) (i) of the Development Costs which were incurred by it in Developing the Products in accordance with the Initial Development Plan or any subsequent Development Plan (excluding costs borne by Lightlake in accordance with Section 3.8.1) and such Development Costs were borne by Adapt prior to the effective date of termination, (ii) the upfront payments paid to Lightlake pursuant to Section 5.1, (iii) the Regulatory Milestones paid to Lightlake pursuant to Section 5.2, (iv) the Sales-Based Milestones paid to Lightlake pursuant to Section 5.3, (iv) and any upfront license payments and milestones paid to Third Parties pursuant to Section 5.5, Lightlake shall pay to Adapt a royalty of [**] percent ([**]%) Net Sales of Product. Sections 5.4.2, 5.5, 5.6, 5.7, 5.8, 5.9, 5.12, 5.13.1 and 5.13.2 shall apply to Lightlake with respect to the Net Sales by Lightlake of Products *mutatis mutandis*, except that all references in the definition of Net Sales to Adapt shall deemed to refer to Lightlake.

10.8.2 In the event of a termination by Adapt pursuant to Section 10.3, Adapt shall continue to pay Lightlake royalties subject to and in accordance with Sections 5.4, and 5.5; provided, however, that each royalty rate contemplated by Sections 5.4.1 and 5.4.2 shall be reduced by [**]% for all royalties owing after the effective date of termination.

10.9 Remedies. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one or more country(ies)) or other

jurisdiction(s) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

10.10 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, (i) Section 10.9 and this Section 10.10 and Articles 7, 9 and 11 of this Agreement shall survive the termination or expiration of this Agreement for any reason, (ii) Sections 3.2.5, 3.3.1(a), 3.3.3(a), 4.1, 4.3.1, 4.3.2, 6.2, 6.3.1, the second sentence of Section 6.4.2(a), Sections 6.4.3(a), 6.4.3(b), 6.5 and 6.6 shall survive any termination of this Agreement other than a termination by Lightlake pursuant to Section 10.3 or Section 10.4 hereof or a termination by Adapt pursuant to Section 10.2 hereof, (iii) Sections 5.4 through 5.9 and Section 10.8.2 shall survive a termination by Adapt pursuant to Section 10.3 hereof, (iv) Article 5 shall survive a termination by Adapt pursuant to Section 10.5 hereof and (v) Sections 10.6, 10.7 and 10.8.1 shall survive any termination of this Agreement by Lightlake pursuant to Section 10.3 or Section 10.4 hereof. With respect to any Sections that survive in accordance with this Section 10.10, the corresponding definitions shall appropriately survive (e.g. the definition of "Term" shall continue with respect to the above noted Sections and usage in other definitions).

ARTICLE XI
MISCELLANEOUS

11.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, acts of God or acts, omissions, or delays in acting by any Governmental Authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement) or similar events beyond the reasonable control of the non-performing Party (a "**Force Majeure**"). The non-performing Party shall notify the other Party of such force majeure within thirty (30) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform.

11.2 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

11.3 Assignment.

11.3.1 Without the prior written consent of Lightlake, Adapt shall not assign, delegate, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided, however*, that Adapt may make such an assignment without Lightlake's prior written consent to its Affiliate or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of all or substantially all the assets or business of Adapt or substantially all of the assets or business of Adapt to which this Agreement relates. With respect to an assignment to an Affiliate, Adapt shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. Without the prior written consent of Adapt, Lightlake shall not assign, delegate, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided, however*, that Lightlake may make such an assignment without Adapt's prior written consent to its Affiliate or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of all or substantially all the assets or business of Lightlake or substantially all of the assets or business of Lightlake to which this Agreement relates. With respect to an assignment to an Affiliate, Lightlake shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. Any attempted assignment or delegation in violation of this Section 11.3 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Lightlake or Adapt, as the case may be. The permitted assignee or permitted transferee shall assume all obligations of its assignor or transferor under this Agreement.

11.3.2 All rights to Information, materials and intellectual property: (i) controlled by a Third Party permitted assignee of a Party, which Information, materials and intellectual property were controlled by such assignee immediately prior to such assignment; or (ii) controlled by an Affiliate of a Party who becomes an Affiliate through any Change in Control of or a merger, acquisition (whether of all of the stock or all or substantially all of the assets of a Person or any operating or business division of a Person) or similar transaction by or with the Party, which Information, materials and intellectual property were controlled by such Affiliate immediately prior thereto, in each case ((i) and (ii)), shall be automatically excluded from the rights licensed or granted to the other Party under this Agreement.

11.4 Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance here from, and (iv) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

11.5 Governing Law. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of New York, United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided, that all questions concerning the construction or effect of patent applications and patents shall be determined in accordance with the laws of the country or other jurisdiction in which the particular patent application or patent has been filed or granted, as the case may be. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

11.6 Dispute Resolution. In the event of any dispute between or among the Parties relating to this Agreement, the Parties will each designate one senior executive to meet and use good faith efforts to attempt to resolve the dispute. If the representatives are unable to resolve the dispute within thirty (30) days following written notice of the dispute from one Party to another, then the Parties shall be free to pursue any remedies available to them at law or in equity.

11.7 Submission to Jurisdiction; Waiver of Jury Trial.

11.7.1 SUBJECT TO SECTION 11.6, IN THE EVENT ANY PARTY TO THIS AGREEMENT COMMENCES ANY LITIGATION, PROCEEDING OR OTHER LEGAL ACTION IN CONNECTION WITH OR RELATING TO THIS AGREEMENT, ANY RELATED AGREEMENT OR ANY MATTERS DESCRIBED OR CONTEMPLATED HEREIN OR THEREIN, WITH RESPECT TO ANY OF THE MATTERS DESCRIBED OR CONTEMPLATED HEREIN OR THEREIN, THE PARTIES TO THIS AGREEMENT HEREBY (A) AGREE THAT ANY LITIGATION, PROCEEDING OR OTHER LEGAL ACTION SHALL BE INSTITUTED IN A COURT OF COMPETENT JURISDICTION LOCATED WITHIN THE BOROUGH OF MANHATTAN, CITY OF NEW YORK, WHETHER A STATE OR FEDERAL COURT; (B) AGREE THAT IN THE EVENT OF ANY SUCH LITIGATION, PROCEEDING OR ACTION, SUCH PARTIES WILL CONSENT AND SUBMIT TO PERSONAL JURISDICTION IN ANY SUCH COURT DESCRIBED IN CLAUSE (A) OF THIS SECTION 11.7 AND TO SERVICE OF PROCESS UPON THEM IN ACCORDANCE WITH THE RULES AND STATUTES GOVERNING SERVICE OF PROCESS (IT BEING UNDERSTOOD THAT NOTHING IN THIS SECTION 11.7 SHALL BE DEEMED TO PREVENT ANY PARTY FROM SEEKING TO REMOVE ANY ACTION TO A FEDERAL COURT IN THE BOROUGH OF MANHATTAN, CITY OF NEW YORK); (C) AGREE TO WAIVE TO THE FULL EXTENT PERMITTED BY LAW ANY OBJECTION THAT THEY MAY NOW OR HEREAFTER HAVE TO THE VENUE OF ANY SUCH LITIGATION, PROCEEDING OR ACTION IN ANY SUCH COURT OR THAT ANY SUCH LITIGATION, PROCEEDING OR ACTION WAS BROUGHT IN AN INCONVENIENT FORUM; (D) DESIGNATE, APPOINT AND DIRECT CT CORPORATION SYSTEM AS ITS AUTHORIZED AGENT TO RECEIVE ON ITS BEHALF SERVICE OF ANY AND ALL PROCESS AND DOCUMENTS IN ANY LEGAL PROCEEDING IN THE STATE OF NEW YORK; (E) AGREE TO NOTIFY THE OTHER PARTIES TO THIS AGREEMENT IMMEDIATELY IF SUCH AGENT SHALL REFUSE TO ACT, OR BE PREVENTED FROM ACTING, AS AGENT AND, IN SUCH EVENT, PROMPTLY TO DESIGNATE ANOTHER AGENT IN THE STATE OF NEW YORK, SATISFACTORY TO BOTH PARTIES, TO SERVE IN PLACE OF SUCH AGENT AND DELIVER TO THE OTHER PARTY WRITTEN EVIDENCE OF SUCH SUBSTITUTE AGENT'S ACCEPTANCE OF SUCH DESIGNATION; (F) AGREE AS AN ALTERNATIVE METHOD OF SERVICE TO SERVICE OF PROCESS IN ANY LEGAL PROCEEDING BY MAILING OF COPIES THEREOF TO SUCH PARTY AT ITS ADDRESS SET FORTH IN SECTION 11.8 FOR COMMUNICATIONS TO SUCH PARTY; (G) AGREE THAT ANY SERVICE MADE AS PROVIDED HEREIN SHALL BE EFFECTIVE AND BINDING SERVICE IN EVERY RESPECT; AND (H) AGREE THAT NOTHING HEREIN SHALL AFFECT THE RIGHTS OF ANY PARTY TO EFFECT SERVICE OF PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.

11.7.2 EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE EACH SUCH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT (INCLUDING ANY SUCH ACTION INVOLVING THE FINANCING SOURCES). EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (i) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (ii) EACH PARTY UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (iii) EACH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (iv) EACH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 11.7.

11.8 Notices.

11.8.1 **Notice Requirements**. Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (i) delivered by hand or sent by facsimile transmission (with transmission confirmed), (ii) by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 11.8.2 or (iii) to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 11.8.1. Such Notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 11.8.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

11.8.2 **Address for Notice.**

If to Adapt, to:

Adapt Pharma Operations Limited
45 Fitzwilliam Square
Dublin 2, Ireland
Attention: Chief Financial Officer

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

Mayer Brown LLP
1675 Broadway
New York, NY 10019
Attention: Reb D. Wheeler
Facsimile: 1-212-849-5914

If to Lightlake, to:

Lightlake Therapeutics
96-98 Baker Street, First Floor
London, England W1U 6TJ
Attention: CEO
Facsimile: +44(0)207 034 1943

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

Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, New Jersey 08540
Attention: David G. Glazer
Facsimile: 1-609-919-6701

11.9 Entire Agreement; Amendments. This Agreement, together with the Schedules attached hereto sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby (including the Existing CDAs). Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

11.10 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

11.11 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

11.12 No Benefit to Third Parties. Covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

11.13 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

11.14 Relationship of the Parties. It is expressly agreed that Lightlake, on the one hand, and Adapt, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture, or agency. Neither Lightlake, on the one hand, nor Adapt, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

11.15 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Adapt or Lightlake are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

11.16 Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

11.17 References. Unless otherwise specified, (i)references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (ii) references in any Section to any clause are references to such clause of such Section, and (iii) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

11.18 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

[SIGNATURE PAGE FOLLOWS.**]**

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

LIGHTLAKE THERAPEUTICS INC.	**ADAPT PHARMA OPERATIONS LIMITED**
By: /s/ Roger Crystal Name: Roger Crystal Title: Chief Executive Officer	By: /s/ Seamus Mulligan Name: Seamus Mulligan Title: CEO

Schedule 1.24

Existing Inventory Supply

Please see attached.

Schedule 1.24

Existing Inventory Supply

PART	STATUS	QUANTITY	EXPECTED
Stoppers	In stock	160,712	-
	On order	1,080,000	Feb-15
Vials	In stock	167,350	-
	On order	85,000	Dec-14
	On order	400,000	Mar-15
Container holder	In stock	79,900	-
	On order	15,000	Dec-14
Actuator	In stock	94,901	-
	On order	-	-
Clinical batch 20mg vials	In stock	65	-
Clinical batch 40mg vials	In stock	150	-
Naloxone API	In stock	6.07kg	-
	On order	-	-

Schedule 1.33

Initial Development Plan

Please see attached.

IN NALOXONE FOR OPIOID OVERDOSE INITIAL DEVELOPMENT PLAN

12 Dec 14

PRIVATE & CONFIDENTIAL

BASIS OF PREPARATION

On the 12 December 2014 the Initial Development Plan assumes a Target Filing Date of the [**]. Achievement of the submission date is based on the following assumptions:

1. [**]
2. [**]
3. [**]
4. [**]
5. [**]
6. [**]
7. [**]

It should be noted that there is inherent uncertainty over our ability to achieve the target submission date as it is contingent on the ability of third party suppliers/service providers to deliver within the required timeframe and other events beyond our control, which could result in delays to the target NDA submission date

Initial Development Plan

Task	Start	Finish	Duration (days)	Status	Months and Years Redacted Months and Years Redacted

[**]

40 lines redacted listing milestones

Schedule 1.52

Product Specific Patents

Please see attached.

Schedule 1.52

Case Number	Title	Country	Case Type	Application No.	Filing Date
LLT0001-101-US	NASAL DRUG PRODUCTS AND METHODS OF THEIR USE	US	Provisional	61/953,379	3/14/2014
LLT0002-101-US	CO-PACKAGED DRUG PRODUCTS	US	Provisional	62/022,268	7/9/2014

Schedule 3.2.3(a)

Adapt Development Tasks

- [**]
- [**]
- [**]
- [**]
- [**]
- [**]
- [**]
- [**]

The above tasks will be completed as required to support an NDA submission to the FDA.

Schedule 3.7

Third Party Service Agreements

- Research and Development Services Agreement between [**] and Lightlake Therapeutics Inc., dated June 23, 2014, and as amended September 9, 2014.

- Clinical Research Agreement between [**] and Lightlake Therapeutics Inc. dated October 7, 2014.

- Consulting Agreement between [**] and Lightlake Therapeutics Inc. dated July 24, 2014, and as amended October 9, 2014.

Schedule 3.8.2

Lightlake Costs

Please see attached.

Schedule 3.8.2 – Lightlake costs

$	As of the Effective Date		
Supplier/Vendor	**Paid**	**Due**	**Total**
[**]	669,457	39,911	**709,368**
[**]	-	357,942	**357,942**
[**]	312,012	-	**312,012**
[**]	40,136	-	**40,136**
[**]	-	76,487	**76,487**
[**]	90,263	11,000	**101,463**
[**]	23,573	21,456	**45,070**
[**]	115,118	14,377	**129,496**
[**]	900	-	**900**
[**]	1,868	-	**1,868**
[**]	28,432	-	**28,432**
[**]	425	-	**425**
Total	**1,282,184**	**521,214**	**1,803,398**

Schedule 7.4

Form of Press Releases

Please see attached.

News Release

Investor Relations Contact:

Amato and Partners, LLC

admin@amatoandpartners.com

LIGHTLAKE THERAPEUTICS INC. ANNOUNCES

LICENSING DEAL WITH ADAPT PHARMA LIMITED SUBSIDIARY

LONDON - (December 16, 2014) - Lightlake Therapeutics Inc. ("Lightlake") (OTCQB: LLTP), a biopharmaceutical company developing addiction treatments based on its expertise in opioid antagonists, announced today that it has entered into a license agreement with Adapt Pharma Operations Limited ("Adapt"), a wholly owned subsidiary of Adapt Pharma Limited, an Ireland-based pharmaceutical company ("Adapt Pharma"). Pursuant to the agreement Adapt has received from Lightlake a global license to develop and commercialize Lightlake's intranasal naloxone opioid over dose reversal treatment. In exchange for licensing its treatment to Adapt, Lightlake could receive potential development and sales milestone payments of more than $55 million, plus up to double-digit royalties.

Lightlake has been developing a nasal spray for the delivery of naloxone that could widely expand its availability and use in preventing opioid overdose deaths, a widespread and under-addressed public health problem in the United States. Lightlake, in collaboration with the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health ("NIH"), commenced a clinical trial with respect to its nasal spray in September 2013. Data from that study showed that using Lightlake's technology naloxone can potentially be delivered into the blood stream at least as quickly as the injection process currently used by hospitals, first responders, and others treating opioid overdoses. In July 2014, Lightlake announced that it had filed an investigational new drug application and received an additional commitment from NIDA to fund a second study with respect to Lightlake's nasal spray. On December 4, 2014, Lightlake announced that this second study had commenced.

"Our entering into an agreement with a subsidiary of Adapt Pharma is a transformative event for Lightlake. Adapt Pharma is a tremendous development and commercialization partner for Lightlake," said Dr. Roger Crystal, CEO of Lightlake. "Adapt Pharma has a highly experienced and proven management team, significant financial resources, and strong capabilities to address a significant public health risk."

"We are pleased to partner with Lightlake and add this product to our business," commented Mr. Seamus Mulligan, Adapt Pharma's Chairman and Chief Executive Officer. "The product is an important therapeutic and will have significant benefits for patients, first responder medical staff and caregivers. We look forward to completing the late stage development and to commercially launching the product."

Torreya Partners LLC acted as financial advisor and Morgan, Lewis & Bockius LLP acted as legal advisor to Lightlake on the transaction.

About Lightlake Therapeutics Inc.

Lightlake Therapeutics Inc., a biopharmaceutical company, is using its expertise in opioid antagonists to build a platform of innovative intranasal naloxone solutions to common addictions and related disorders. Lightlake is developing a treatment to reverse opioid overdoses, which have reached epidemic proportions in the United States. Lightlake has completed a clinical trial for this treatment in collaboration with the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health, and has commenced a second study in collaboration with NIDA. Lightlake also has completed a Phase II clinical trial to treat Binge Eating Disorder. For more information please visit: http://www.lightlaketherapeutics.com.

About Adapt Pharma Limited

Adapt Pharma Limited is a privately held pharmaceutical company committed to positively impacting the lives of patients with specialist medical conditions. Adapt Pharma's strategy is to identify, evaluate, selectively acquire and enhance the value of late stage development, and FDA approved, pharmaceutical products. Adapt Pharma's company headquarters are in Dublin, Ireland. For more information please visit http://www.adaptpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed, implied or inferred by these forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "would," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions based on our current expectations and projections about future events. You should not place undue reliance on these statements. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors. These and other factors may cause our actual results to differ materially from any forward-looking statement. We undertake no obligation to update any of the forward-looking statements after the date of this press release to conform those statements to reflect the occurrence of unanticipated events, except as required by applicable law.

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Adapt Pharma Announces License Agreement for Intranasal Naloxone with Lightlake Therapeutics Inc.

Dublin, Ireland - December 16th, 2014 - Adapt Pharma Limited ("Adapt Pharma") today announced the signing of a License Agreement for global rights and related intellectual property to develop and commercialize intranasal naloxone for the treatment of opioid overdose with Lightlake Therapeutics Inc. ("Lightlake") (OTCQB: LLTP).

Naloxone is an opioid antagonist used for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Opioid overdose can occur in various settings, including overdose with prescription pain medications such as morphine or through the use of illegal drugs such as heroin. An injectable formulation of naloxone is currently approved by the U.S. Food and Drug Administration. Adapt Pharma believes that an intranasal formulation may facilitate the earlier administration of naloxone, particularly by family members, caregivers and first responder emergency personnel.

The nasal spray formulation of naloxone has been in development by Lightlake. Lightlake, in collaboration with the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health ("NIH"), commenced a clinical trial with respect to the nasal spray in September 2013. In July 2014, Lightlake announced that it had filed an investigational new drug application and received an additional commitment from NIDA to fund a second study. On December 4, 2014, Lightlake announced that this second study had commenced.

"We are pleased to partner with Lightlake and add this product to our business," commented Mr. Seamus Mulligan, Adapt Pharma's Chairman and Chief Executive Officer. "The product may be an important therapeutic with significant benefits for patients, first responder medical staff and caregivers. We look forward to completing development and commercially launching the product."

"Our entering into an agreement with Adapt is a transformative event for Lightlake. Adapt is a tremendous development and commercialization partner for Lightlake," said Dr. Roger Crystal, CEO of Lightlake. "Adapt has a highly experienced and proven management team, significant financial resources, and strong capabilities to address a significant public health risk."

About Adapt Pharma Limited
Adapt Pharma Limited is a privately held pharmaceutical company committed to positively impacting the lives of patients with specialist medical conditions. Adapt Pharma's strategy is to identify, evaluate, selectively acquire and enhance the value of late stage development, and FDA approved, pharmaceutical products. Adapt Pharma's company headquarters are in Dublin, Ireland. For more information please visit http://www.adaptpharma.com

About Lightlake Therapeutics Inc.
Lightlake Therapeutics Inc., a biopharmaceutical company, is using its expertise in opioid antagonists to build a platform of innovative intranasal naloxone solutions to common addictions and related disorders. For more information please visit: http://www.lightlaketherapeutics.com.

Media Contact Details
Mr. David Clerkin, Gordon MRM
Tel: +353-87-830-1779
Email: adapt@gordonmrm.ie

Schedule 8.2.10

Relevant Contracts

Please see attached.

- Research and Development Services Agreement between [**] and Lightlake Therapeutics Inc., dated June 23, 2014, and as amended September 9, 2014.

- Clinical Research Agreement between [**] and Lightlake Therapeutics Inc. dated October 7, 2014.

- Consulting Agreement between [**] and Lightlake Therapeutics Inc. dated July 24, 2014, and as amended October 9, 2014.

- Master Consultancy Services Agreement between [**] and Lightlake Therapeutics Inc. dated August 2, 2014.

- Mutual Nondisclosure Agreement between [**] and Lightlake Therapeutics Inc. dated April 17, 2014., including the Appendix A - Schedule of Fees for Ad-hoc Services

- Clinical Trial Agreement between Lightlake Therapeutics Inc. and the Division of Pharmacotherapies and Medical Consequences of Drug Abuse, National Institute on Drug Abuse dated January 31, 2013.

EXHIBIT A

FORM OF CONSENT FOR ASSIGNMENT

December __, 2014

Re: Consent to Assignment of [INSERT NAME OF ASSIGNED CONTRACT]

Dear Sir/Madam:

We are excited to advise you that Lightlake Therapeutics Inc. ("Lightlake") has entered into an agreement with Adapt Pharma Operations Limited ("Adapt") in which it has exclusively licensed its intranasal naloxone product to Adapt for treatment of opioid overdose ("Product"). The transaction closed on December , 2014. With respect to such license, Adapt will continue the development and commercialization of the Product.

We are writing this letter to request that you consent to the assignment of Lightlake's rights under the [INSERT THE NAME OF THE CONTRACT] between [INSERT NAME OF COUNTERPARTY] ("Counterparty") and Lightlake dated [INSERT DATE OF AGREEMENT] ("Agreement") to Adapt, and to Adapt's assumption of any and all obligations of Lightlake to Counterparty arising on or after the effective date of such assignment and assumption.

Please execute this letter in the space provided below as evidence of Counterparty's (i) consent to assignment of the Agreement to Adapt, and Adapt's assumption of Lightlake's obligations to Counterparty thereunder arising on or after the effective date of such assignment and assumption, (ii) confirmation that the Agreement will continue in full force and effect in accordance with its terms following the assignment and (iii) waiver of any of Counterparty' rights with respect to such assignment and transfer.

Please return to my attention a copy of the signed consent by email to roger.crystal@lightlaketherapeutics.com and mail the original to our office. If you have any questions, please do not hesitate to call me.

Sincerely,

Lightlake Therapeutics Inc.

By:

Name: Roger Crystal
Title: CEO

Consented to this ___ day of , 2014:

[INSERT NAME OF THIRD PARTY]

By:

Name:

Title:

EXHIBIT B
FORM OF ASSIGNMENT AND ASSUMPTION AGREEMENT

ASSIGNMENT AND ASSUMPTION AGREEMENT

This **ASSIGNMENT AND ASSUMPTION AGREEMENT** ("Agreement") is made and entered into as of December ___, 2014 (the "Effective Date") by and between Lightlake Therapeutics Inc., a Nevada corporation ("Lightlake"), and Adapt Pharma Operations Limited, an Irish limited company ("Adapt"). Lightlake and Adapt are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, the Parties are entering into to the License Agreement (the "License Agreement") with respect to a intranasal naloxone product for treatment of opioid overdose (the "Product"); and

WHEREAS, subject to the terms and conditions contained herein and in the License Agreement,

Lightlake wishes to assign and transfer to Adapt, and Adapt wishes to receive from and assume (effective as of the Effective Date), all of the rights and obligations of Lightlake under certain agreements relating to the Product.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Defined Terms**. All capitalized terms used in this Agreement (other than the headings of the Sections) shall have the meanings set forth in this Agreement, or, if not specifically defined in this Agreement, shall have the same meanings as defined in the License Agreement. Whenever used in this Agreement: (a) the words "include," "includes" or "including" shall be construed as incorporating also the phrase "but not limited to" or "without limitation" and shall mean including without limiting the generality of any description preceding or following such words; (b) the word "day" shall mean a calendar day unless specified otherwise; (c) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including the Exhibits attached to this Agreement); and (d) words in the singular include the plural and vice versa.

2. **Assignment and Assumption of Assigned Agreements**.

2.1 Assignment. Lightlake hereby assigns, transfers, sets over and conveys to Adapt all of Lightlake's rights, title, interests, and benefits in, to and under the agreements set forth on Exhibit A (each, an "Assigned Agreement", and collectively, the "Assigned Agreements"), as a whole, on and after the Effective Date.

2.2 **Acceptance and Assumption**. Adapt hereby accepts the assignment of the Assigned Agreements and assumes, effective on the Effective Date, all rights, licenses, privileges, liabilities and obligations under each Assigned Agreement arising on or after the Effective Date, with the exception of any liability or obligation attributable to a breach of any Assigned Agreement by Lightlake.

3. **Governing Law**. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of New York, United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided, that all questions concerning the construction or effect of patent applications and patents shall be determined in accordance with the laws of the country or other jurisdiction in which the particular patent application or patent has been filed or granted, as the case may be. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods

4. **Entire Agreement; Amendment and Waiver**. This Agreement, together with the License Agreement, constitutes the entire agreement among the Parties with respect to the subject matter hereof and supersedes all prior oral or written agreements, representations, understandings or arrangements among the Parties relating thereto. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by all Parties. No waiver of any rights under this Agreement shall be effective unless in writing signed by the Party to be charged. A waiver of a breach or violation of any provision of this Agreement will not constitute or be construed as a waiver of any subsequent breach or violation of that provision or as a waiver of any breach or violation of any other provision of this Agreement.

5. **Severability**. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance here from and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

6. **Further Assurances**. Each Party shall, as and when requested by the other Party, do all acts and execute all documents as may be reasonably necessary to give effect to the provisions of this Agreement.

7. **No Partnership**. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, joint venture, or employer-employee relationship among the Parties. Neither Lightlake nor Adapt (or their Affiliates) shall incur any debts or make any commitments for the other Party, except to the extent, if at all, specifically provided herein.

8. **Counterparts; Electronic Execution**. This Agreement may be executed in two (2) or more counterparts, both of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail. Facsimile or PDF signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

****

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

LIGHTLAKE THERAPEUTICS INC.	**ADAPT PHARMA OPERATIONS LIMITED**
By: Name: Title:	By: Name: Title:

Exhibit A

Assigned Agreements

- Research and Development Services Agreement between [**] and Lightlake Therapeutics Inc., dated June 23, 2014.

- Clinical Research Agreement between [**] and Lightlake Therapeutics Inc. dated October 7, 2014.

- Consulting Agreement between [**] and Lightlake Therapeutics Inc. dated July 24, 2014, and as amended October 9, 2014.

EXHIBIT 10.52

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

Execution Version

AMENDMENT NO. 1 TO LICENSE AGREEMENT

This Amendment No. 1 to License Agreement (this "**Amendment**") is made as of December 13, 2016, by and among Opiant Pharmaceuticals Inc. (formerly known as Lightlake Therapeutics Inc.), a Nevada corporation ("**Opiant**"), and Adapt Pharma Operations Limited, an Irish limited company ("**Adapt**"). Opiant and Adapt are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**". Capitalized terms used but not defined herein have the meanings given to them in the License Agreement (as defined below).

RECITALS

WHEREAS, the Parties entered into a License Agreement, dated as of December 15, 2014 (including the exhibits and schedules thereto, the "**License Agreement**"), pursuant to which Opiant licenses to Adapt certain intellectual property rights to develop and commercialize Products in accordance with the terms and conditions set forth therein;

WHEREAS, Section 11.9 of the License Agreement provides that no amendment or modification to the License Agreement shall be binding upon the Parties unless in writing and duly executed by authorized representations of both Parties; and WHEREAS, the Parties desire to amend, modify and supplement the License Agreement in the manner specified in this Amendment.

NOW, THEREFORE, for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

1. Amendment to Lightlake References. Each instance of "Lightlake" appearing in the Agreement, including where such word is used as part of other defined terms, but excluding instances where such word is used as part of "Lightlake Therapeutics Inc.", is hereby replaced with "Opiant".

2. Amendment to Section 1.11 of the License Agreement. Section 1.11 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"1.11 "**Commercial Sublicensee**" means a Sublicensee to whom Adapt has granted a right to offer for sale, have sold or sell one or more Products in all or a portion of the Territory including exclusive distributors, but excluding (i) Persons who Manufacture Product(s) or any element thereof and sell such Product(s) only to or at the direction of Adapt, Sublicensees or any of their respective Affiliates, (ii) wholesalers, (iii) pharmacies, (iv) Persons comprising the First Responder Market, (v) any Person performing third party logistics or warehousing services on behalf of Adapt or its Affiliates or Sublicensees, and (vi) any other Person who does not have any obligation to make an upfront, milestone, royalty or similar payment with respect to the applicable Products."

3. Amendment to Section 1.30 of the License Agreement. Section 1.30 of the License Agreement is hereby amended by deleting clause (i) thereof and replacing such clause (i) with the following:

"(i) is sold by a Third Party (or any of such Third Party's direct or indirect licensees or sublicensees) that is not a licensee or a Commercial Sublicensee of Adapt or its Affiliates (A) in the United States, under an Abbreviated New Drug Application (ANDA), (B) in the European Union, pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or (C) in any other country or jurisdiction, pursuant to all equivalents of such provisions".

4. Amendment to Section 3.3.1(b) of the License Agreement. Section 3.3.1(b) of the License Agreement is hereby amended by (a) deleting the phrase "recall," from the first sentence thereof and (b) deleting the word "such" from the second sentence thereof.

5. Amendment to Section 3.5.2 of the License Agreement. Section 3.5.2 of the License Agreement is hereby amended by deleting the first sentence thereof and replacing such sentence with the following:

"Once a Product receives all requisite Regulatory Approvals in the United States necessary to Commercialize such Product therein, Adapt shall use Commercially Reasonable Efforts to Commercialize such Product in the United States."

6. Amendment to Section 3.6.2 of the License Agreement. Section 3.6.2 of the License Agreement is hereby amended by deleting the words "and Commercial Sublicensees" from the first sentence thereof.

7. Amendment to Section 4.3.1 of the License Agreement. Section 4.3.1 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"4.3.1 Right to Grant Sublicenses. Adapt shall have the right to grant Sublicenses (through multiple tiers of Sublicensees). Adapt shall cause each Sublicensee to comply with the applicable terms and conditions of this Agreement. Adapt shall remain responsible for the performance of its Affiliates and Sublicensees that are granted Sublicenses as permitted herein, and the grant of any such Sublicense shall not relieve Adapt of its obligations under this Agreement. With respect to any such Sublicense, Adapt shall ensure that the agreement pursuant to which it grants such Sublicense (i) does not conflict with the terms and conditions of this Agreement and (ii) contains terms obligating the Sublicensee to comply with

confidentiality and non-use provisions consistent with those set forth in this Agreement. With respect to any such Sublicense to a Commercial Sublicensee that grants such Commercial Sublicensee rights to Commercialize a Product in the United States, Adapt shall use Commercially Reasonable Efforts to ensure that the agreement pursuant to which it grants such Sublicense contains (A) terms obligating such Commercial Sublicensee to permit Opiant rights of inspection, access, and audit substantially similar to those provided to Opiant in this Agreement and (B) terms relating to intellectual property and data ownership consistent with those set forth in this Agreement. With respect to any such Sublicense to a Commercial Sublicensee that grants such Commercial Sublicensee rights to Commercialize a Product in the United States, Adapt shall ensure that the agreement pursuant to which it grants such sublicense contains an exclusivity provision consistent with that contained in Section 4.6.2. A copy of any Sublicense agreement with a Commercial Sublicensee executed by Adapt shall be provided to Opiant within fourteen (14) days after its execution; *provided* that the financial terms of any such Sublicense agreement may be redacted to the extent not pertinent to an understanding of a Party's obligations or benefits under this Agreement."

8. Amendment to Section 4.3.2 of the License Agreement. Section 4.3.2 of the License Agreement is hereby amended by replacing the first instance of the word "In" therein with the following: "Subject to the provisions of Section 10.11, in".

9. Amendment to Section 4.6.2 of the License Agreement. Section 4.6.2 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"4.6.2 During the term of any agreement pursuant to which a Commercial Sublicensee is granted a Sublicense to sell a Product in the United States or have a Product sold in the United States, other than as contemplated by this Agreement, each Party shall cause such Commercial Sublicensee not to (i) directly or indirectly, develop, commercialize or manufacture any Competing Product in the United States, or (ii) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly, develop, commercialize or manufacture any Competing Product in the United States."

10. Amendments to Article 6 of the License Agreement.

(a) Section 6.3 of the License Agreement is hereby amended by adding a new Section 6.3.4 thereto, immediately after Section 6.3.3, as follows:

"6.3.4 Commercial Sublicensees. Anything to the contrary herein notwithstanding, Adapt shall have the right to assign its rights and delegate its obligations under this Section 6.3 with respect to Patents in any country or territory outside the United States to any Commercial Sublicensee to whom Adapt has granted a right to sell the Product in such country or territory. In such event, Adapt shall remain responsible for ensuring that such Commercial Sublicensee performs any such delegated obligations in accordance with the terms of this Section 6.3, as applicable."

(b) Section 6.4 of the License Agreement is hereby amended by adding a new Section 6.4.5 thereto, immediately after Section 6.4.4, as follows:

"6.4.5 Commercial Sublicensees. Anything to the contrary herein notwithstanding. Adapt shall have the right to assign its rights and delegate its obligations under Sections 6.4.2 and Section 6.4.3 with respect to actual or suspected infringement or misappropriation in any country or territory outside the United States to any Commercial Sublicensee to whom Adapt has granted a right to sell the Product in such country or territory. In such event, Adapt shall remain responsible for ensuring that such Commercial Sublicensee performs any such delegated obligations in accordance with the terms of Section 6.4.2 and 6.4.3, as applicable."

(c) Section 6.5 of the License Agreement is hereby amended by adding the words "As between the parties." immediately prior to the first occurrence of "Adapt" therein.

11. Amendment to Section 7.5 of the License Agreement. Section 7.5 of the License Agreement is hereby amended by deleting the phrase "and Lightlake shall be provided with a copy of any such Publication in advance of public publication or presentation thereof and Adapt shall consider in good faith any comments Lightlake may have with respect thereto" from the second sentence thereof.

12. Amendments to Article 10 of the License Agreement.

(a) Section 10.3 of the License Agreement is hereby amended by adding the following as a new final sentence thereof: "Notwithstanding the foregoing, in no event shall Opiant have the right to terminate this Agreement on the basis of any breach of any term hereof by a Sublicensee or attributable to the action or inaction of a Sublicensee."

(b) Section 10.4 of the License Agreement is hereby amended by deleting the words "or Commercial Sublicensees" and "or Commercial Sublicensee" therein.

(c) Section 10.6 of the License Agreement is hereby amended by replacing the first instance of the word "In" therein with the following: "Subject to Section 10.11, in".

(d) Section 10.6.5 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"10.6.5 at Opiant's request and subject to the terms of any applicable third party agreement, assign to Opiant all right, title and interest of Adapt in each Product Trademark at Adapt's expense: and".

(e) Section 10.10 of the License Agreement is hereby amended by adding ", Section 10.11" after "Section 10.10" in clause (i) thereof.

(f) Article 10 of the License Agreement is hereby amended by adding the following after Section 10.10 thereof:

"10.11 Step-In Rights. If this Agreement is properly terminated by Opiant pursuant to Sections 10.3, 10.4 or 10.5, then, provided that such Commercial Sublicensee is not then in material breach of the agreement pursuant to which its Sublicense has been granted (the **"Sublicense Agreement"),** any Commercial Sublicensee may (in its sole discretion), within thirty (30) days of receiving notice of such termination, upon written notice to Opiant and Adapt, elect to become a direct licensee of Opiant under rights and terms equivalent to the rights and terms of such Sublicense Agreement, effective from and after the effective date of such termination of this Agreement; provided that such Commercial Sublicensee shall not have any rights greater than the rights granted to Adapt under this Agreement and Opiant shall have no obligations under such Sublicense Agreement to such Commercial Sublicensee in excess of its obligations to Adapt. In the event that this Section 10.11 is invoked in respect of a particular Commercial Sublicensee, the references to Sublicensees and Commercial Sublicensees in Sections 10.6.3 and 10.6.4 shall thereupon be deemed not to refer to such Commercial Sublicensee in respect of which this Section 10.11 is invoked. If requested by Adapt, Opiant shall enter into a reasonable and customary letter agreement with any Commercial Sublicensee and Adapt containing terms consistent with this Section 10.11 and other terms reasonably acceptable to Opiant, Adapt and such Commercial Sublicensee."

13. Amendment to Section 11.8.2 of the License Agreement. Section 11.8.2 of the License Agreement is hereby amended by replacing the address for notice of Opiant set forth therein with the following:

If to Opiant, to:

Opiant Pharmaceuticals Inc.
401 Wilshire Blvd., 12th Floor
Santa Monica, CA 90401
Attention: CEO
Facsimile: 1-917-322-2105

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

DLA Piper LLP (US)
1650 Market Street, Suite 4900
Philadelphia, PA 19103
Attention: Fahd M.T. Riaz
Facsimile: 1-215-606-2069

14. Amendment to Section 11.12 of the License Agreement. Section 11.12 of the License Agreement is hereby amended by replacing the word '"Covenants" therein with the following: "Except as otherwise provided in Section 10.11 hereof, covenants".

15. Possible Future Amendments. If requested by Adapt in connection with the granting of a Sublicense to a Commercial Sublicensee in respect of Europe and/or the United Kingdom, the Parties shall promptly negotiate in good faith additional amendments to the License Agreement necessary to implement the changes to the financial terms of the License Agreement that are contemplated on Exhibit A to this Amendment, or such other terms as the Parties may mutually agree upon in good faith.

16. References in the License Agreement. All references in the License Agreement to "this Agreement" shall mean the License Agreement as amended by this Amendment.

17. Limitation of Amendment and Affirmation of License Agreement. Except as expressly provided herein, this Amendment shall not be deemed to be a waiver or modification of any term, condition or covenant of the License Agreement. Any conflict between the terms herein and in the License Agreement shall be governed by the terms of this Amendment. Except as expressly amended hereby, all terms and conditions set forth in the License Agreement are hereby affirmed by the Parties and shall remain in full force and effect.

18. Incorporation by Reference. The provisions of Sections 11.3.1, 11.4, 11.5, 11.6, , 11.8, 11.10, 11.11, 11.12, 11.13, 11.14, 11.16 and 11.18 of the License Agreement are hereby incorporated by this reference, *mutatis mutandis,* as if the provisions were fully set forth herein.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Amendment is hereby executed by the authorized representatives of the Parties as of the date first written above.

OPIANT PHARMACEUTICALS, INC.

By: /s/ Roger Crystal

Name: Roger Crystal

Title: CEO

ADAPT PHARMA OPERATIONS LIMITED

By: /s/ David Brabazon

Name: David Brabazon

Title: Director

EXHIBIT A

In the event that Adapt proposes to enter into an agreement with a Commercial Sublicensee who would Exploit a Product in the European Union and/or the United Kingdom (as applicable, "Europe"), at Adapt's request, the Parties will negotiate in good faith to amend the License Agreement as necessary to implement the terms described below.

Term	**Addition or Modification**
Revenue sharing	Opiant (or its designee) would share in royalties, milestone payments and payments for any supplied Product, less all costs incurred in generating such European revenues (including, amongst others, development, regulatory, licensing, safety, supply and distribution costs attributable to Europe) received by Adapt from a Sublicensee in Europe ("Europe Net Revenues") based on the following: • [**]% of all such amounts, up to $[**] of cumulative revenue; and • [**]% of all such amounts in excess of $[**] in cumulative revenue. In the event that Opiant (or its designee) does not receive the $[**] milestone contemplated by Section 5.2.4 of the License Agreement, then the $[**] threshold contemplated above shall be reduced to $[**]. Amounts comprising Europe Net Revenues and revenues earned by any Sublicensee in Europe would be excluded for purposes of determining Net Sales on which Opiant (or its designee) would otherwise be entitled to royalties under the License Agreement, subject to the provisions set forth below in Global Sales Milestones and Royalty Tiers. Adapt shall make the revenue share payments in respect of the Europe Net Revenues to Opiant (or its designee) on a Calendar Quarter basis in accordance with the terms of Section 5.6 of the License Agreement and any other written instructions agreed to by Adapt.
Global Sales Milestones and Royalty Tiers	Europe Net Revenues received by Adapt from any Sublicensee in Europe would be included for purposes of determining Net Sales giving rise to sales-based milestones pursuant to Section 5.3.1 of the License Agreement and for purposes of determining royalty tiers set forth in Section 5.4.1 of the License Agreement. Sublicensee revenues in Europe would be excluded for purposes of such determinations. The $75 million Annual Net Sales Milestone Threshold specified in Section 5.3.1 of the License Agreement would be changed to $74 million. The $200 million Annual Net Sales Milestone Threshold specified in Section 5.3.1 of the License Agreement would be changed to $ 185 million.

EXHIBIT 21

LIST OF SUBSIDIARIES

Name of Subsidiary	Jurisdiction of Incorporation or Organization
Domestic	
400 Professional LLC	Delaware
Cangene bioPharma, LLC	Maryland
Emergent Commercial Operations Frederick Inc.	Maryland
Emergent Biodefense Operations Lansing LLC	Delaware
Emergent Europe Inc.	Delaware
Emergent International Inc.	Delaware
Emergent Manufacturing Operations Baltimore LLC	Delaware
Emergent Product Development Gaithersburg Inc.	Delaware
Emergent Protective Products USA Inc.	Delaware
Emergent Virology LLC	Delaware
PaxVax Inc.	Delaware
Adapt Pharma Inc.	Delaware
International	
3579299 Manitoba Ltd.	Manitoba
Adapt Pharma Limited	Ireland
Adapt Pharma Canada Ltd.	British Columbia
Adapt Pharma Operations Limited	Ireland
Emergent Acquisition Limited	Ireland
Emergent BioSolutions Canada Inc. (f/k/a Cangene Corporation)	Ontario
Emergent BioSolutions Malaysia SDN. BHD.	Malaysia
Emergent BioSolutions Portugal, LDA	Portugal
Emergent Countermeasures International Ltd.	England
Emergent Global Health Foundation Limited	England
Emergent Italy S.r.l.	Italy
Emergent Netherlands B.V.	Netherlands
Emergent Product Development Germany GmbH	Germany
Emergent Product Development UK Limited	England
Emergent Sales and Marketing Australia Pty Ltd.	Australia
Emergent Sales and Marketing France S.A.S.	France
Emergent Sales and Marketing Germany GmbH	Germany
Emergent Sales and Marketing Singapore Pte. Ltd.	Singapore
PaxVax Ltd.	England
PaxVax AUS Pty. Ltd.	Australia
PaxVax Bermuda Ltd.	Bermuda
PaxVax Berna GmbH	Switzerland
PaxVax Holding Company, Ltd.	Cayman Islands
PaxVax Spain, S.L.	Spain

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-139190) pertaining to the Employee Stock Option Plan, as amended and restated, the 2006 Stock Incentive Plan and individual director options agreements of Emergent BioSolutions, Inc.,
(2) Registration Statement (Form S-8 No. 333-161154) pertaining to the Amended and Restated 2006 Stock Incentive Plan of Emergent BioSolutions Inc.,
(3) Registration Statement (Form S-4 No. 333-169351) of Emergent BioSolutions Inc. and Subsidiaries,
(4) Registration Statement (Form S-3 No. 333-181133) of Emergent BioSolutions Inc. and Subsidiaries,
(5) Registration Statement (Form S-8 No. 333-184699) pertaining to the 2012 Employee Stock Purchase Plan and the Second Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan,
(6) Registration Statement (Form S-8 No. 333-196232) pertaining to the Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan,
(7) Registration Statement (Form S-3 No. 333-204405) of Emergent BioSolutions Inc. and Subsidiaries, and
(8) Registration Statement (Form S-8 No. 333-216294) pertaining to the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan;
(9) Registration Statement (Form S-8 No. 333-225283) pertaining to the Emergent BioSolutions Inc. Stock Incentive Plan, and
(10) Registration Statement (Form S-3 No. 333-226544) of Emergent BioSolutions Inc. and Subsidiaries.

of our reports dated February 21, 2019, with respect to the consolidated financial statements and schedule of Emergent BioSolutions Inc. and subsidiaries and the effectiveness of internal control over financial reporting of Emergent BioSolutions Inc. and subsidiaries included in this Annual Report (Form 10-K) of Emergent BioSolutions Inc. and subsidiaries for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Baltimore, Maryland
February 21, 2019

EXHIBIT 31.1

CERTIFICATION

I, Daniel Abdun-Nabi certify that:

1. I have reviewed this Annual Report on Form 10-K of Emergent BioSolutions 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 functions):

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

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

Date: February 21, 2019

/s/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Richard S. Lindahl certify that:

1. I have reviewed this Annual Report on Form 10-K of Emergent BioSolutions 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 functions):

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

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

Date: February 21, 2019

/s/RICHARD S. LINDAHL
Richard S. Lindahl
Chief Financial 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 on Form 10-K of Emergent BioSolutions Inc. (the "Company") for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel Abdun-Nabi, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(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 21, 2019

/s/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
Chief Executive Officer

EXHIBIT 32.2

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 on Form 10-K of Emergent BioSolutions Inc. (the "Company") for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard S. Lindahl, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(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 21, 2019

/s/RICHARD S. LINDAHL
Richard S. Lindahl
Chief Financial Officer