UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event Reported): January 12, 2021

Amphastar Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36509**	**33-0702205**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

11570 6th Street **Rancho Cucamonga, California**	**91730**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(909) 980-9484**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AMPH	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 7.01. Regulation FD Disclosure

On January 12, 2021, Amphastar Pharmaceuticals, Inc. (the "**Company**"), released an updated investor presentation of the Company's business model, products, and product candidates. The investor presentation will be used from time to time in meetings with investors.

A copy of the above-referenced presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information furnished pursuant to Item 7.01 of this current report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing. The furnishing of the information in this Current Report on Form 8-K is not intended to, and does not, constitute a determination or admission by the Company that the information in this Current Report on Form 8-K is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Investor presentation of Amphastar Pharmaceuticals, Inc. dated January 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AMPHASTAR PHARMACEUTICALS, INC.

Date: January 12, 2021

By: **/S/WILLIAM J. PETERS**
William J. Peters
Chief Financial Officer and Senior Vice President

Exhibit 99.1

Investor Presentation
January 2021

Forward Looking Statements

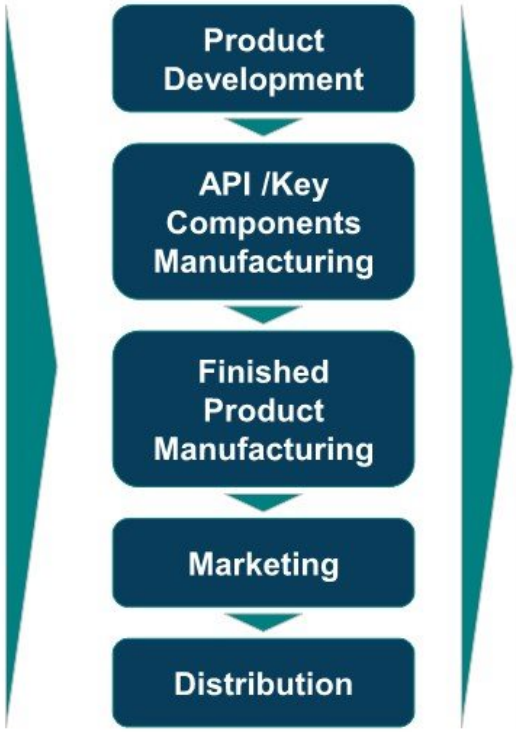
This presentation and the accompanying oral presentation contain forward-looking statements that are based on our management's current expectations and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including, but not limited to, information concerning our business plans and objectives, potential growth opportunities, product development, regulatory approvals, market potential, efficiencies, competitive position, and industry environment, among other statements.

All statements in this presentation that are not historical are forward-looking statements, including, among other things, statements relating to the Company's expectations regarding future financial performance, backlog, sales and marketing of its products, market size and growth, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to its pipeline of product candidates, its share buyback program and other future events, such as the impact of the COVID-19 pandemic and related responses of business and governments to the pandemic on our operations and personnel, and on commercial activity and demand across our business operations and results of operations. These statements are not historical facts but rather are based on Amphastar's historical performance and its current expectations, estimates, and projections regarding Amphastar's business, operations and other similar or related factors. Words such as "may," "might," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expect," "intend," "plan," "project," "believe," "estimate," and other similar or related expressions are used to identify these forward-looking statements, although not all forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond Amphastar's control. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in Amphastar's filings with the Securities and Exchange Commission, including in the Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 16, 2020. In particular, the extent of COVID-19's impact on our business will depend on several factors, including the severity, duration and extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic, all of which continue to evolve and remain uncertain at this time. You can locate these reports through the Company's website at http://ir.amphastar.com and on the SEC's website at www.sec.gov. The forward-looking statements in this presentation speak only as of the date of the presentation. Amphastar undertakes no obligation to revise or update information in this presentation or the conference call referenced above to reflect events or circumstances in the future, even if new information becomes available or if subsequent events cause Amphastar's expectations to change.

You should not rely upon forward-looking statements as predictions of future events. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur as forward-looking statements are inherently susceptible to uncertainty and changes in circumstances as with any projections or forecasts. Moreover, neither we, nor any other person, assume responsibility for the accuracy and completeness of the forward-looking statements. Any forward-looking statements made by us in this presentation speak only as of the date of this presentation, and we undertake no obligation to update any forward-looking statements for any reason after the date of this presentation, except as required by law.

Fully Integrated Business Model

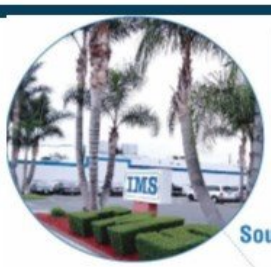
- Extensive in-house product development capabilities
  - Strong product development
  - State-of-the-art instruments
  - Animal studies
  - Clinical research team
- Fully integrated back end manufacturing capabilities
  - API and starting materials
  - Key components
- Complete front end integration
  - Marketing
  - Distribution



- Control over quality and compliance throughout the product development and manufacturing cycle

Company Overview: Amphastar Facilities

Vertically integrated from R&D to clinical trials, manufacturing, marketing and distribution



IMS
South El Monte, CA
U.S.A

Armstrong
Canton, MA
U.S.A

Amphastar
Rancho Cucamonga, CA
U.S.A

ANP
Nanjing
Jiangsu,
China

NDRC
Chino, CA
U.S.A

AFP
Eragny-sur-Epte,
France

Focus on Products With High Technical Barriers

Products with:

- **Large markets**
- **High technical barriers to entry**

Focused on:

- **Injectables**
- **Inhalation**
- **Biosimilar**
- **Interchangeable**

High Technical Barriers to Entry

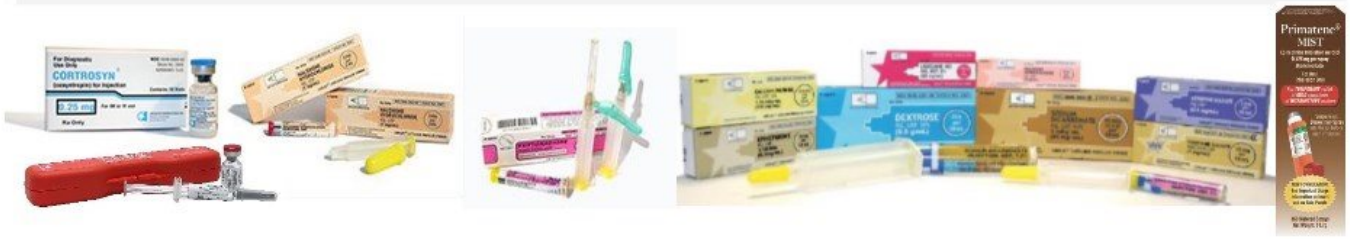
- Scarcity of API requires unique synthetic or rDNA capabilities
- Characterization for complex molecules
- Immunogenicity studies for proteins and complex molecules
- Difficult or complex manufacturing processes
- Proprietary delivery technologies: PFS, MDI, IN and sustained release
- Particle engineering from nm to µm
- Innovative formulations

Company Overview: Milestones of Pipeline Development

Drug Name	Regulatory	Indication	Description
Hyaluronidase	NDA→BLA	Adjuvant	Protein, injectable
Enoxaparin	ANDA	Deep Vein Thrombosis	Polysaccharide, injectable, combination product
Primatene MIST®	NDA	Intermittent Asthma	Asthma inhaler, OTC, MDI, combination product
Glucagon	ANDA	Hypoglycemia	Highly purified peptide, injectable; emergency use combination product

Company Overview: Commercial Product Portfolio

- Diverse core of over 20 commercial products
- Injectable and MDI products; including complex, combination products
- Indications include: deep vein thrombosis, asthma, opioid overdose, pain management, anesthesia and hypoglycemia
  - Enoxaparin
  - Glucagon
  - Lidocaine Injection and Jelly
  - Vitamin K1
  - Naloxone
  - Primatene MIST®
  - Medroxyprogesterone
  - Epinephrine
  - Cortrosyn®
- Consistent revenues and cash flow



Company Overview: Sales and Gross Profit Trend

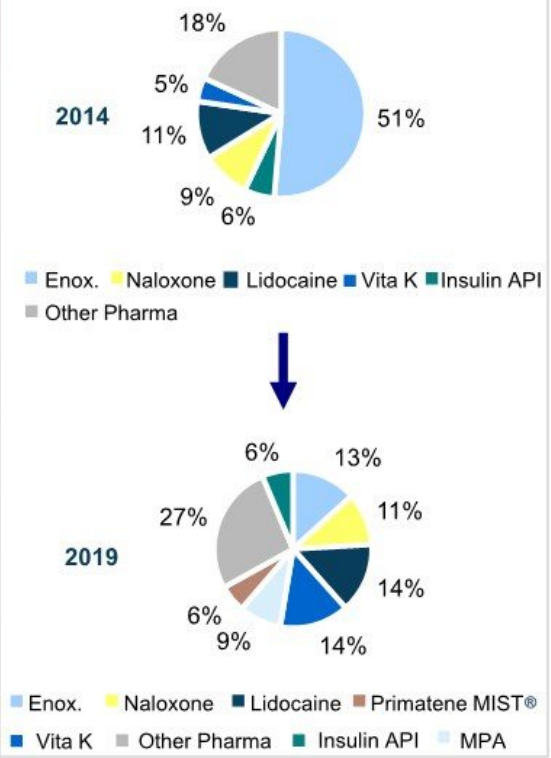
Historical Net Revenue

Historical Gross Profit

Existing Products Provide Strong Base

Products	Net Revenue ($ Millions)	
	2018	2019
Naloxone	$37	$35
Lidocaine	$43	$46
Vitamin K1	$42	$46
Enoxaparin	$53	$43
Medroxyprogesterone (MPA)	$24	$28
Primatene MIST®	$4	$18
Other Pharma Products	$68	$86
Insulin API	$24	$20
Total	$295	$322

Diversified Revenue



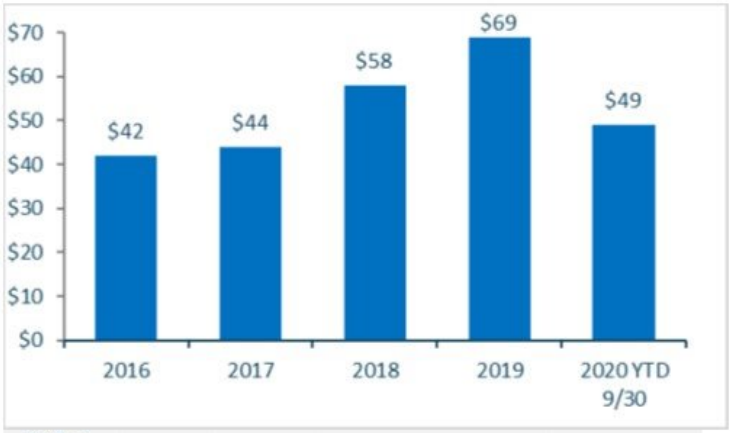
Amphastar

Focused on R & D Investment

- Strategic focus to make substantial R&D investments to expand our product portfolio and grow our business
- Leveraging technical capabilities and/or identify and develop high-margin opportunities
- We believe our emphasis and investment in R&D differentiates us from our competitors as our focus is on the long-term growth of our company
- We have over 300 employees dedicated to R&D

Self-funded R&D investment of approximately $262 million in the recent 5 years

($ millions)

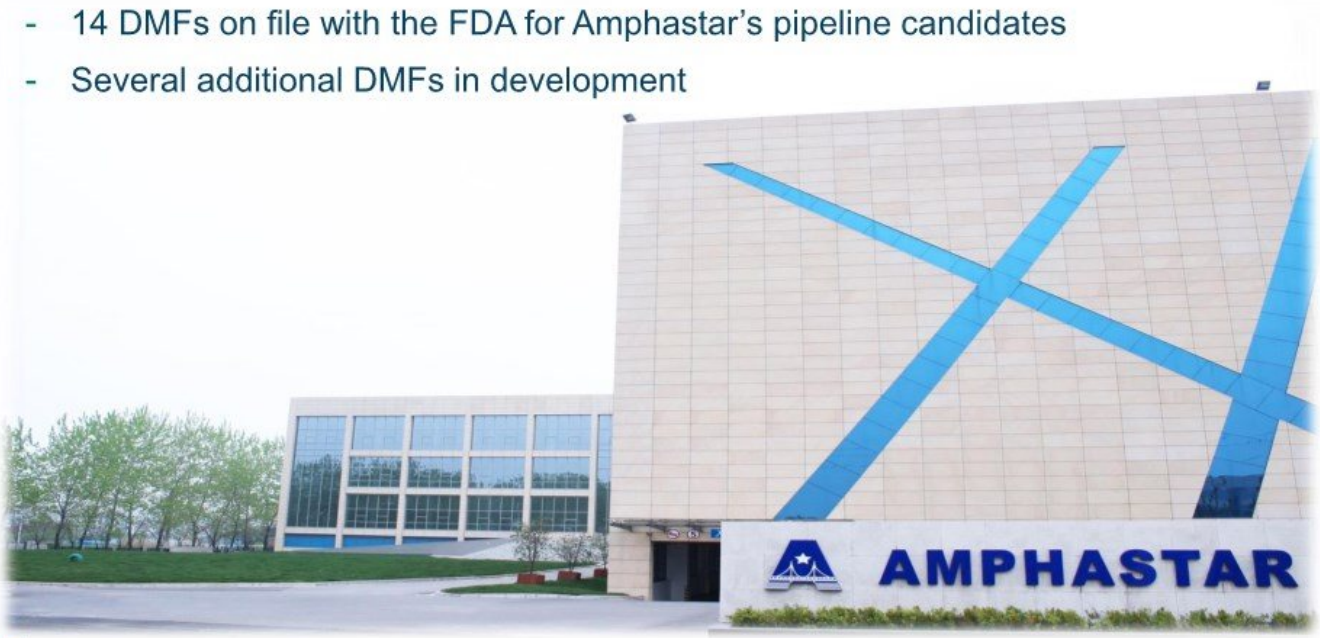


R&D as % of Revenue	15%	18%	20%	21%	19%

Amphastar

Amphastar Nanjing Pharmaceuticals (ANP) Overview

- **Established to provide APIs and starting materials to Amphastar**
- **Current portfolio of APIs and starting materials**
  - 4 FDA approvals for Amphastar's NDA/ANDA
  - 14 DMFs on file with the FDA for Amphastar's pipeline candidates
  - Several additional DMFs in development



Amphastar Nanjing Pharmaceuticals (ANP) Development

- **Sold 42% of ANP ownership for $57 million in 2018 to fund:**
  - ANP's API facility including rDNA products
  - Manufacturing and selling API and finished product to the China market

Pipeline – ANDA with Technical Barriers

Generic Pipeline, 12 Candidates with Technical Barriers

- **Four filed ANDAs** with IQVIA* sales of approximately $1.6 Billion including:
  - AMP 002 – High technical barrier product with > $300 mm IQVIA sales and no approved generics
    - Received CRL 12/2020, and plan to respond in Q1 2021
  - Currently on file for generic Lexiscan® and Vasostrict®
  - AMP-006 - Injectable product with IQVIA sales > $50 mm
- **Three Injectable ANDAs** in development targeting products with IQVIA sales of approximately $3 Billion
- **Five Inhalation ANDAs** in development targeting products with IQVIA sales of approximately $8 Billion
- Most of them with technical barriers
- Technical Platforms to be used: characterization, particle-engineering, sustained-release, peptide technology and immunogenicity

*IQVIA sales with TTM as of September 30, 2020

Pipeline – Insulin and Proteins, Biologics License Applications (BLAs)

Insulins and Proteins, Biosimilar and/or Interchangeable

- Three candidates of Insulins ("Insulin Program") and Proteins
- Significant US market: IQVIA sales ~$13 Billion, ~130 millions of units
- Need sophisticated rDNA technology, state-of-the-art analytical technology, and significant investment on development
- Regulatory route: Biological License Application (BLA) 351(k) (Biosimilar) and aim at Interchangeable Insulin
- Recent FDA Guidance

"… if a comparative analytical assessment based on state-of-the-art technology supports a demonstration of "highly similar" for a proposed biosimilar or interchangeable insulin product, there would be little or no residual uncertainty regarding immunogenicity; in such instances, the proposed biosimilar or interchangeable insulin product, like the reference product, would be expected to have minimal or no risk of clinical impact from immunogenicity. **In such instances, a comparative clinical immunogenicity study generally would be unnecessary to support a demonstration of biosimilarity or interchangeability.**" (FDA Guidance, November 2019, Emphasis Added.)

Pipeline – Insulin and Proteins, BLAs

Insulins and Proteins, Biosimilar and/or Interchangeable

- FDA Guidance established regulatory route by analytical assessment based on state-of-the-art technology supports a demonstration of “highly similar” and heavy clinical study for immunogenicity would be “unnecessary”
- API Manufacturing: rDNA technology, by AFP and ANP
- First INDs for the Insulin Program have been filed or in the process to file;
- Clinical program for an IND in the Insulin Program is in process
- Cost of clinical program for Insulin products could potentially be significantly reduced

Pipeline – Proprietary Pipeline, New Drug Applications (NDAs)

Proprietary Pipeline NDA

- Development of innovative proprietary products requires sophisticated technology
- Amphastar's proven R&D and technical platforms support the development of proprietary pipeline candidates
- Amphastar has expertise in clinical studies to support the NDA development; the NDA 505(b)(2) regulatory route requires clinical studies with a smaller sample size
- Naloxone Intranasal, NDA is pending, planned response to CRL in 2021;
- Epinephrine Intranasal, Phase I study completed with successful results
- Two candidates are in active development phase
- More pipeline candidates are in the early stage

Glucagon for Injection Kit Launch

- The first and only FDA approved generic Glucagon for Injection in 20 years
- Highly-purified synthetic peptide product was determined by FDA to be bioequivalent and therapeutically equivalent to Eli Lilly's Glucagon Emergency Kit, which has recombinant DNA (rDNA) origin
- Highlights the Company's sophisticated characterization technology
- Commercial launch planned within two months of approval
- Sales of Eli Lilly's Glucagon Emergency Kit were approximately $144 million*

*IQVIA 12 months ended September 30, 2020

Primatene MIST® History

- Primatene MIST®, a proprietary and patent protected over-the-counter epinephrine inhalation product
- The only FDA approved asthma inhaler available OTC
- Purchased U.S. trademark from Wyeth in 2008
- Intensive cardiovascular studies >40,000 data points
- Special label design for the OTC setting (extensive human factors label studies)
- Approved November 2018, launched December 2018

Primatene MIST® Marketing Update

- Improvements from Primatene MIST® CFC
  - Higher delivery efficiency, with improved efficacy at a lower dose
  - Dose indicator
  - Aluminum container instead of glass
  - HFA propellant replaces CFC
- Effective TV and Radio advertising campaign began in July 2019 with national coverage
- Multiple scientific articles were published in support of safe and effective use

Available OTC nationwide at:

amazon

CVS pharmacy

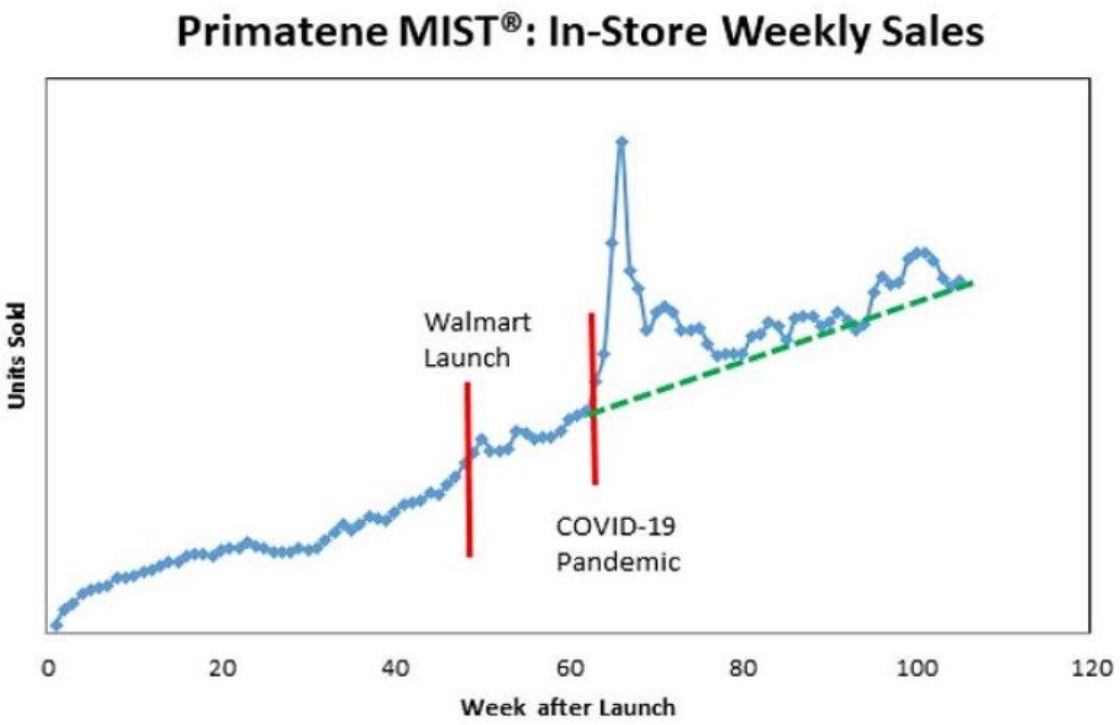
Kroger

RITE AID

Walgreens

Walmart

Primatene MIST®: Sales Trend



Near-Term Growth Points in 2021

- Glucagon Injection Kit launch planned February 2021
- Primatene MIST® indicated for "intermittent asthma"
  - Adult asthma patients: 19.2 million per CDC*
  - Intermittent adult asthma patients: ~35% (per CDC**), or 6.7 million
- Epinephrine multi-dose vials launched May 2020

*https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm;
**https://www.cdc.gov/asthma/asthma_stats/severity_adult.htm

Strong Balance Sheet

Capitalization as of September 30, 2020	
($ 000s)	
Cash, cash equivalents, restricted cash and short-term investments	$102,848
Long-term debt, including current portion	$45,070
Total stockholders' equity	$450,962

Investment Highlights

- Biopharmaceutical company focused on development and manufacturing of technically-challenging BLAs, NDAs, and ANDAs in injectable, inhalable and intranasal formulations
- Strong base business with approximately $322 million in 2019 revenue and approximately $132 million in 2019 gross profit
- Robust pipeline of over 20 product candidates, including the insulin products, in markets with barriers to entry
- Advanced technical capabilities and multiple delivery technologies proven through the successful development and launch of enoxaparin, glucagon, medroxyprogesterone and Primatene MIST®
- Vertically integrated infrastructure and technical expertise for products with high barriers to market entry
- ANP (Nanjing) development strengthens our vertically integrated infrastructure and technical expertise for products with high barriers to market entry
- Successful track record of company and product acquisitions
- Experienced management team with deep scientific experience