### **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): October 3, 2018

### **Eagle Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation)

001-36306 (Commission File Number)

20-8179278 (IRS Employer Identification No.)

50 Tice Boulevard, Suite 315 Woodcliff Lake, NJ

07677 (Zip Code)

(Address of principal executive offices)

Registrant's telephone number, including area code: (201) 326-5300

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company o

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. o

#### Item 7.01 Regulation FD Disclosure.

On October 3, 2018, Eagle Pharmaceuticals, Inc., or the Company, will present the attached discussion of the Company's business model, products, and product candidates at the Cantor Fitzgerald Global Healthcare Conference in New York, New York, being held October 1–3, 2018.

A copy of the above-referenced presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information furnished pursuant to Item 7.01 of this current report, including Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended. As such, this information shall not be incorporated by reference into any of the Company's reports or other filings made with the Securities and Exchange Commission. The furnishing of the information in this current report is not intended to, and does not, constitute a determination or admission by the Company that the information in this current report 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. Presentation of the Company dated October 2018

99.1

Description

#### **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.

Eagle Pharmaceuticals, Inc.

Dated: October 3, 2018

By: /s/ Scott Tarriff

Scott Tarriff

Chief Executive Officer

# Eagle Pharmaceuticals

October 2018



## Forward Looking Statements

This presentation contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words such as "will" "underway." "allow," "expect(ed)." "pursuing," "may," "would." "addressing," "creating." "intends," "anticipate(s)," "plan," "partner," "could," "enables," "potential(ly)," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements grading future events such as: the continued commercial performance of our marketed products, including but not limited to BENDEKA, which is marketed by our partner l'eav, Ryanodex, which we market ourselves, as well as our ability to replicate our marketing successes for our other product candidates such as Ryanodex for EHS or other additional indications, our pemetrexed candidate, our bendamustine candidate, our bendamustine candidate, our bendamustine candidate, our bendamustine ranchise; the strength of our cash position and the ability to optimize the deployment of capital and take advantage of market opportunities; the continued year over year growth of our revenue, EBITDA, adjusted non-GAAP earnings per share and profit margins; the continued growth of the global biologics market and our ability to use the Arsia Therapeutics (now Eagle Biologics) to enter into the biologics market and to effectively carry out our strategy in this new market; the contribution of the Ryanodex portfolio to our growth; the timing of Ryanodex for EHS obtaining EDA approval, if ever, and, entering the market; and the advancement or any of our other product candidates including, but not limited to, fulvestrant and pemetrexed, through the development process including FDA approval and the ability of any such products to have commercial success and to access significant new markets. All of such statements are subject to certain risks and uncertainties, many of which



## Non-GAAP Financial Performance Measures

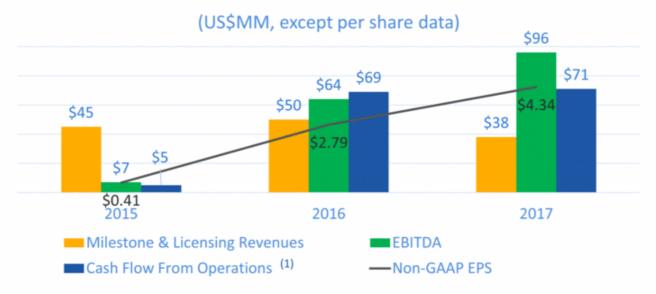
In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted net income and adjusted earnings per share from continuing operations attributable to the Company. The Company believes these measures provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

Adjusted net income from continuing operations excludes share-based compensation expense, depreciation, amortization of acquired intangible assets, changes in contingent purchase price, non-cash interest expense and tax adjustments. The Company believes these non-GAAP financial measures help indicate underlying trends in the Company's business and are important in comparing current results with prior period results understanding projected operating performance. Non-GAAP financial measures provide the Company and its investors with an indication of the Company's baseline performance before items that are considered by the Company not to be reflective of the Company's ongoing results. See the following Reconciliation of GAAP to Adjusted Net Income and Adjusted Earnings per Share and Reconciliation of GAAP to Adjusted Non-GAAP EBITDA for explanations of the amounts excluded and included to arrive at adjusted net income and adjusted earnings per share amounts, and adjusted non-GAAP EBITDA amounts, respectively, for the twelve months ended December 31, 2017, 2016 and 2015.

These adjusted measures are non-GAAP and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. The Company strongly encourages investors to review its consolidated financial statements and publicly-filed reports in their entirety and cautions investors that the non-GAAP measures used by the Company may differ from similar measures used by other companies, even when similar terms are used to identify such measures.



# Significant Growth since IPO



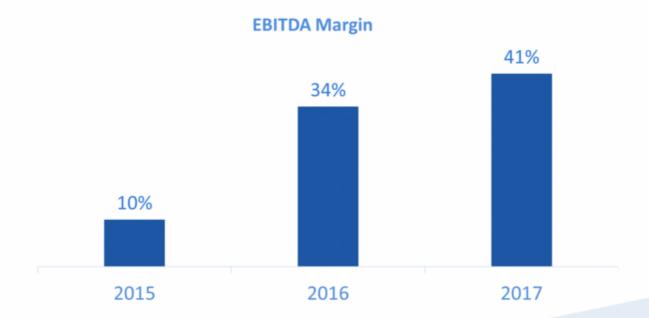
- #16 on Fortune's 100 List of Fastest-Growing Companies with #1 ranking for both 3-year EPS and revenue growth
- CF from Operations (1) expected to significantly increase in 2018

(1) Cash Flow excludes receivables build

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# Strong EBITDA Margin





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## 2018 to date:

## 1st half of 2018

- First-to-file Vasopressin ANDA
- Launched 500 ml bendamustine ("big bag")
- Orphan Drug Exclusivity granted

## 2nd half of 2018

- EHS enrollment of 2<sup>nd</sup> study completed; preliminary analysis of the data replicated treatment effect of 2015 Hajj
- Nerve agent: signed CRADA with US Military
- EA-111 (IM product in RYANODEX® franchise)
- Biostudy planning ongoing for second ANDA
- Fulvestrant



## RYANODEX®: Multiple Label Expansion Opportunities

Creating additional value by addressing life-threatening, unmet needs Eight patents issued to date expiring from 2022 to 2025

#### Marketed

### **Potential Label Expansion**

### Malignant Hyperthermia

- Breakthrough formulation of dantrolene sodium
- Approved in July 2014; launched in August 2014



#### **Exertional Heat Stroke**

- Completed enrollment of 2<sup>nd</sup> safety and efficacy study
  - Meet with FDA to discuss next steps
- Potential to be the first drug to market for EHS
  - A hyperthermic/hypermetabolic condition related to MH
- Orphan Drug Designation
- Plan to meet with FDA to discuss next steps

#### **Nerve Agent**

- Treatment of neurological damage secondary to nerve agent exposure as potential next indication
- Positive results of an initial study to evaluate the neuroprotective effects of RYANODEX in an established rodent model

Progress being made to an IM version of RYANODEX



## RYANODEX for Exertional Heat Stroke

- P-value of 0.05 means that study results reported are 95% due to treatment effect rather than randomness
- Treatment effect observed after two distinct trials, regardless of sample size:
  - p -value of .07-.08
  - 92%-93% chance that the results we have are not random
  - · Treatment effect is clinically meaningful
- Believe we further removed randomness, duplicated results of 2015 study with similar study results from 2<sup>nd</sup> Hajj study
  - Mathematical separation between active and control group
- No drugs on the market to treat EHS
  - Orphan Drug Designation
  - · Fast Track and Priority Review
- Confident RYANODEX works as anticipated and plan to meeting with FDA as soon as possible

6:1 odds ratio
6 fold likelihood that
patient will have full
CNS recovery using
RYANODEX
compared to
standard of care
cooling alone

Additional indications for Ryanodex under review with more information to be provided at the appropriate times



# RYANODEX for the Treatment of Nerve Agent Exposure

- Nerve agent (NA) exposure is often deadly; survivors frequently experience severe neurological consequences
- Q4 2018: Entered into agreement with the United States Army Medical Research Institute of Chemical Defense (USAMRICD)
  - Study to evaluate the neuroprotective effects of RYANODEX
- · GLP Study Design:
  - Treatment will include the current standard of care, atropine and oxime
  - · Randomized to receive RYANODEX or a control vehicle as added treatment
  - · Potentially pivotal trial

If approved, RYANODEX would be a first of its kind neuroprotective treatment for the amelioration of neurological damage due to NA exposure

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# RYANODEX for NA Pilot Study Summary

- Over 50 rodents exposed to a high dose of the NA soman
  - · Treated with the known antidote for acute poisoning (atropine and HI-6)
  - All surviving study rodents developed severe status epilepticus and were treated with standard AEDs according to protocol
- Study rodents were randomly assigned to receive RYANODEX or control vehicle as added treatment
- · No safety issues were observed
- Rodents treated with RYANODEX + AEDs had better performance in neurobehavioral testing, compared to animals treated with AEDs only, and substantially less brain damage
  - · Showed substantially lower level of brain cell necrosis
  - Rodents treated with standard therapy showed a mean necrosis score of 2.6 in fronto-parietal cortex, compared to a group of RYANODEX treated rodents showing a score of 0.6 in the same anatomical region
  - The scoring system for cell necrosis ranges between 0 (normal, no necrosis) to 5 (cellular necrosis greater than 80%)



# Seven Year Orphan Drug Exclusivity (ODE) Granted for BENDEKA by Court

- U.S. District Court for the District of Columbia issued a decision requiring FDA to grant seven years of ODE in the U.S. for BENDEKA
- FDA will not be able to approve any drug applications referencing BENDEKA until ODE expires in December 2022
- Generic TREANDA® entry now not expected until December 2022
- Further Protects Longevity of BENDEKA franchise



## Bendamustine Long Life Cycle

## **Orphan Drug Exclusivity Granted**

## 2016 - 2025

- Improved product profile and unique J-code for BENDEKA
- 15 OB listed patents through 2033
- Up to 97% market share for BENDEKA
- BENDEKA Royalty of 25% of US net sales (increased from 20% in Q4 2016)
- FDA approval for 2<sup>nd</sup> manufacturing site
- TREANDA generics not expected before December 2022
- Expansion to OUS markets (20% royalty)
- Launched "big bag" with potential market share of up to 12%

### Significant BENDEKA royalties and milestones earned

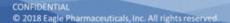
- 1/1/15-6/30/18: **\$126 mm** in aggregate milestones earned
- 1/1/16-6/30/18: \$303 mm in royalties earned



# Fifteen Orange Book Patents Running from 2026-2033 Protecting the longevity of the bendamustine franchise

| U.S. Patent No.                                | Patent Expiration |
|--|-------------------|
| 8,609,707                                      | 1/28/2031         |
| 8,791,270*PED                                  | 7/12/2026         |
| (owned by Teva Pharmaceutical Industries Ltd.) |                   |
| 9,000,021                                      | 3/15/2033         |
| 9,034,908                                      | 3/15/2033         |
| 9,144,568                                      | 3/15/2033         |
| 9,265,831                                      | 1/28/2031         |
| 9,572,796                                      | 1/28/2031         |
| 9,572,797                                      | 1/28/2031         |
| 9,572,887                                      | 3/15/2033         |
| 9,579,384                                      | 3/15/2033         |
| 9,579,397                                      | 3/15/2033         |
| 9,579,398                                      | 3/15/2033         |
| 9,579,399                                      | 3/15/2033         |
| 10,010,533                                     | 1/28/2031         |
| 10,052,385                                     | 3/15/2033         |

Eagle/Teva asserting all patents challenged by ANDA filers



EAGLE

# Launch of "big bag"

# Ready-to-dilute (RTD) bendamustine hydrochloride (HCl) solution

- 500 ml admixture for the treatment of patients with CLL and NHL
- Launched our ready-to-dilute product with our internal sales force
- Expands our bendamustine product offering and is complementary to BENDEKA
- Enables us to provide value to a cost-conscious segment of the market
- Anticipate over time achieving up to a 12% market share



## **Fulvestrant Opportunity**

## INDICATIONS for FASLODEX®

Label expanded in the U.S. to first line breast cancer in August 2017

### Monotherapy

FASLODEX is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy, or HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy

### **Combination Therapy**

FASLODEX in combination with palbociclib is indicated for the treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in women with disease progression after endocrine therapy.

- Currently marketed by AstraZeneca
- Administered monthly in a doctor's office as 2 separate intramuscular injections, one in each buttock
- FDA has recently required revising the FASLODEX label

Faslodex \* is a registered trademark of AstraZeneca.

EAGLE PHARMACEUTICALS

## The Problem

- 2 deep intramuscular injections of high viscosity product per dose of treatment (5 mL each)
- Administered over 1-2 minutes into each buttock
- · Painful procedure
- FASLODEX injection reactions have been associated with peripheral nerve adverse reactions, including risk of damaging the sciatic nerve



#### WARNINGS AND PRECAUTIONS

#### 5.3 Injection Site Reaction

Injection site related events including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy have been reported with FASLODEX injection. Caution should be taken while administering FASLODEX at the dorsogluteal injection site due to the proximity of the underlying sciatic nerve.



## Pemetrexed Opportunity

- At this time, Lilly's Alimta patent litigations prevent current ANDA filers from launching until May 24, 2022
- FDA granted tentative approval of Eagle's Pemetrexed RTD PEMFEXY™ Oct. 27, 2017
- Lilly sued Eagle on August 14, 2017. Trial scheduled to begin on Sept. 9, 2019; 30 month stay February 2020.
- There are four 505(b)(2) filers (DRL, Hospira, Actavis/Teva, Apotex) with a similar approach to Eagle's (ours appears to be a differentiated product)
  - DRL and Hospira both filed Motions for Summary Judgment of Noninfringement in late July 2017
    - · DRL's summary judgment motion was denied
    - · Hospira's summary judgment briefing scheduled to be completed in Q4 2018
  - DRL went to trial in February 2018. We anticipate a decision by Q4 2018. Hospira trial scheduled to begin Dec. 3, 2018
  - Apotex was sued in August 2017. Trial is presumptively scheduled for July 2019
  - Eagle continues evaluating all litigations and outcomes
- Multi-billion market opportunity (LTM Sales: \$1.06B U.S., \$1.04B Ex-U.S., \$2.10B WW)<sup>1</sup>

<sup>1</sup>Alimta® (pemetrexed) (Eli Lilly & Co.). Source: Eli Lily & Company Quarterly Results; Statements of Consolidated Income – As Reported, Q2 2018; <a href="https://investor.lilly.com/results.cfm">https://investor.lilly.com/results.cfm</a>



## Eagle Biologics Market Opportunity

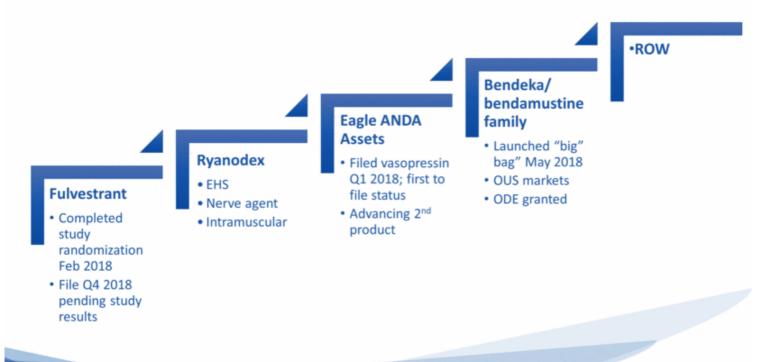
- · Acquired Arsia Therapeutics in 2016
  - Enhances Eagle's formulation capabilities and expands product development opportunities
  - Extends Eagle's strategy: plan to partner with key Biosimilar or Bioinnovator companies to alter their existing pipeline into "Biobetters"
  - \$45 million investment
- The global biologics market could exceed \$390 billion in value over the next five years<sup>1</sup>
- Growing at nearly 2X the rate of pharma<sup>1</sup>
- By the end of 2020, biologics could account for 28% of the global pharmaceuticals market<sup>1</sup>
- The global biosimilar market may reach \$20 \$26 billion by 2020<sup>2</sup>

References: 1. PRA Health Sciences Whitepaper. The Value of Biobetters. December 2015. 2. IMS Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020. April 2015.

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# 2018 & Beyond: Poised for Growth

Multiple potential regulatory filings in 2018



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## Financial Highlights

### As of 06/30/18

LTM 6/30/18 EBITDA: \$72.5 mm

• Cash: \$100.2 mm

A/R: \$69.4 mm

- Share Repurchase Plan
  - \$103.5 mm repurchased (1.6 mm shares at \$65.37) since August 2016
    - \$12 million during August and September 2018; majority purchased after EHS data release
  - \$100 mm additional authorization approved by the Board August 2017
- 14.9 mm basic shares outstanding (at 09/30/18)
- \$150 mm credit facility August 2017
  - \$100 mm term loan (\$47.5 mm outstanding at 06/30/18)
  - \$50 mm revolver



# Thank You

October 2018



# **APPENDIX**



## Reconciliation of GAAP to Adjusted Non-GAAP Net Income

|   |     | 2015    |    | nths Ended Dec<br>2016 |    | 2017    |  |
|---|-----|---------|----|------------------------|----|---------|--|
| Net income from operations - GAAP                     | S   | 2,571   | \$ | 81,453                 | s  | 51,94   |  |
| Before tax adjustments:                               |     |         |    |                        |    |         |  |
| Cost of product revenues:                             |     |         |    |                        |    |         |  |
| Amortization of acquired intangible assets (1)        |     |         |    | 746                    |    | 1,19    |  |
| Gain on sale of asset (2)                             |     |         |    | (1,750)                |    |         |  |
| Research and development:                             |     |         |    |                        |    |         |  |
| Share-based compensation expense                      |     |         |    | 2,914                  |    | 3,94    |  |
| Depreciation  |     |         |    |                        |    | 7       |  |
| Expense of acquired in-process research & developme   | ent |         |    |                        |    | 1,00    |  |
| Selling, general and administrative:                  |     |         |    |                        |    |         |  |
| Share-based compensation expense                      |     | 4,051   |    | 6,853                  |    | 11,48   |  |
| Amortization of acquired intangible assets (3)        |     |         |    | 203                    |    | 1,62    |  |
| Depreciation  |     | 112     |    | 640                    |    | 85      |  |
| Debt issuance costs                                   |     |         |    | -                      |    | 28      |  |
| Severance   |     |         |    |                        |    | 26      |  |
| Other:  |     |         |    |                        |    |         |  |
| Non-cash interest expense                             |     |         |    | 8                      |    | 23      |  |
| Changes in fair value of contingent consideration (4) |     |         |    | 957                    |    | (7,37   |  |
| Asset impairment charge                               |     |         |    | -                      |    | 7,23    |  |
| Legal Settlement                                      |     |         |    |                        |    | 1,65    |  |
| Tax adjustments (5)                                   |     |         |    | (46,103)               |    | (5,36   |  |
| Adjusted Non-GAAP net income                          | S   | 6,734   | \$ | 45,921                 | \$ | 69,04   |  |
| Adjusted Non-GAAP earnings per share                  |     |         |    |                        |    |         |  |
| Basic   | s   | 0.44    | s  | 2.96                   | s  | 4.5     |  |
| Diluted   | S   | 0.41    | S  | 2.79                   | S  | 4.3     |  |
| Weighted number of common shares outstanding:         |     |         |    |                        |    |         |  |
| Basic   | 15. | 250,154 | 15 | ,533,681               | 15 | ,102,89 |  |
| Diluted   | 16. | 253,781 | 16 | ,434,104               | 15 | ,908,21 |  |

#### **Explanation of Adjustments:**

- Amortization of intangible assets for Ryanodex and Docetaxel
- Gain on divestiture of diclofenacmisoprostol
- Amortization of intangible assets for Eagle Biologics
- Changes in the fair value of contingent consideration (Docetaxel and Eagle Biologics)
- 5) Reflects the estimated tax effect of the pretax adjustments, \$3.4 million of tax expense from U.S. tax reform which is reflected in fourth quarter of 2017 and the reversal of a tax valuation allowance in the fourth quarter of 2016



# Reconciliation of GAAP to Adjusted Non-GAAP EBITDA

|   |          | e Months I | Months Ended |  |  |
|---|----------|------------|--------------|--|--|
| (in thousands)  | 2015     | 2016       | 2017         |  |  |
| Net income from operations - GAAP                     | \$ 2,571 | \$ 81,453  | \$ 51,943    |  |  |
| Tet meone non operations - oraci                      | 0 2,071  | 001,400    | 001,040      |  |  |
| Add back:   |          |            |              |  |  |
| Interest expense (income), net                        | (14)     | (76)       | 1,045        |  |  |
| Provision for income taxes                            | 3        | (28,026)   | 21,002       |  |  |
| Depreciation and amortization                         | 112      | 1,589      | 3,746        |  |  |
|   |          |            |              |  |  |
| Add back:   |          |            | -            |  |  |
| Stock-based compensation                              | 4,051    | 9,768      | 15,429       |  |  |
| Changes in fair value of contingent consideration     | -        | 957        | (7,378       |  |  |
| Debt issuance costs                                   |          |            | 286          |  |  |
| Asset impairment charges                              |          | -          | 7,235        |  |  |
| Gain on sale of asset                                 |          | (1,750)    | -            |  |  |
| Expense of acquired in-process research & development |          |            | 1,000        |  |  |
| Severance   |          |            | 268          |  |  |
| Legal Settlement                                      |          |            | 1,650        |  |  |
|   |          |            |              |  |  |
| Adjusted Non-GAAP EBITDA                              | \$ 6,723 | \$63,915   | \$ 96,226    |  |  |

