

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

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FORM 10-Q

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(Mark one)

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

For the quarterly period ended September 30, 2015

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 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

06-1614015

(I.R.S. employer  
identification no.)

708 Quince Orchard Road, Suite 205, Gaithersburg, MD

(Address of principal executive offices)

20878

(Zip code)

Registrant's telephone number, including area code: (240) 813-1260

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

12,539,704 shares of the Company's common stock, par value \$0.01 per share, were outstanding as of October 30, 2015.

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OPGEN, INC.

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## INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q of OpGen, Inc. and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In this Form 10-Q, we refer to OpGen, Inc. as the “Company,” “we,” “our” or “us.” All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect” or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II Item 1A “Risk Factors.” In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the commercialization of our current products, including our QuickFISH® and PNAFISH diagnostic products for infectious diseases, Acuitas® MDRO test products and completed development and commercialization of our Acuitas Lighthouse™ MDRO Management System products and services;
- integration of the operations of AdvanDx, Inc. acquired by merger on July 14, 2015;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- changes in laws or regulations applicable to our business, including potential regulation by the FDA;
- our ability to develop and commercialize new products and the timing of commercialization;
- our liquidity and working capital requirements, including our long-term future cash requirements beyond the next 12 months; and
- our expectations regarding future revenue and expenses.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statement made by us in this quarterly report on Form 10-Q speaks only as of the date on which it is made. We disclaim any duty to update any of these forward looking statements after the date of this quarterly report on Form 10-Q to confirm these statements to actual results or revised expectations.

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to this quarterly report on Form 10-Q, including the factors described in Part II. Item 1A. “Risk Factors,” as well as our quarterly reports on Form 10-Q for the periods ended June 30, 2015 and March 31, 2015 filed with the United States Securities and Exchange Commission, or SEC. Other risks may be described from time to time in our filings made under the securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this quarterly report on Form 10-Q speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

**OpGen, Inc.**  
**Condensed Consolidated Balance Sheets**  
**(unaudited)**

|   | September 30,<br>2015 | December 31,<br>2014 |
|---|-----------------------|----------------------|
| <b>Assets</b>   |                       |                      |
| <b>Current assets</b>   |                       |                      |
| Cash and cash equivalents   | \$ 11,187,129         | \$ 749,517           |
| Accounts receivable, net  | 553,938               | 503,983              |
| Inventory, net  | 1,155,488             | 369,742              |
| Prepaid expenses and other current assets   | 538,312               | 90,233               |
| <b>Total current assets</b>   | <b>13,434,867</b>     | <b>1,713,475</b>     |
| Property and equipment, net   | 1,021,971             | 587,956              |
| Deferred IPO issuance costs   | -                     | 296,041              |
| Intangible assets, net  | 1,955,769             | -                    |
| Goodwill  | 291,747               | -                    |
| Other noncurrent assets   | 293,135               | 57,459               |
| <b>Total assets</b>   | <b>\$ 16,997,489</b>  | <b>\$ 2,654,931</b>  |
| <b>Liabilities, Redeemable Preferred Stock and Stockholders' Equity (Deficit)</b>   |                       |                      |
| <b>Current liabilities</b>  |                       |                      |
| Accounts payable  | \$ 1,274,657          | \$ 1,160,081         |
| Accrued compensation and benefits   | 840,637               | 423,099              |
| Accrued liabilities   | 1,232,328             | 993,657              |
| Deferred revenue  | 158,860               | 339,171              |
| Short-term notes payable  | 1,250                 | 1,505,000            |
| Current maturities of long-term capital lease obligations   | 227,049               | 100,499              |
| Short-term convertible notes, net of discounts  | -                     | 1,500,000            |
| <b>Total current liabilities</b>  | <b>3,734,781</b>      | <b>6,021,507</b>     |
| Note payable  | 1,000,000             | -                    |
| Long-term capital lease obligations and other noncurrent liabilities  | 317,854               | 134,149              |
| <b>Total liabilities</b>  | <b>5,052,635</b>      | <b>6,155,656</b>     |
| <b>Commitments and contingencies (Note 10)</b>  |                       |                      |
| <b>Redeemable convertible preferred stock</b>   |                       |                      |
| Series A redeemable convertible preferred stock, \$.01 par value; 6,000,000 shares authorized; 3,999,864 shares issued and outstanding at December 31, 2014 (none at September 30, 2015); aggregate liquidation preference of \$7,999,728 at December 31, 2014 (none at September 30, 2015) | -                     | 4,564,899            |
| <b>Total redeemable convertible preferred stock</b>   | <b>-</b>              | <b>4,564,899</b>     |
| <b>Stockholders' equity (deficit)</b>   |                       |                      |
| Common stock, \$.01 par value; 200,000,000 shares authorized; 12,539,704 and 493,178 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively  | 125,397               | 4,932                |
| Additional paid-in capital  | 121,216,140           | 88,701,737           |
| Accumulated other comprehensive loss  | (49)                  | -                    |
| Accumulated deficit   | (109,396,634)         | (96,772,293)         |
| <b>Total stockholders' equity (deficit)</b>   | <b>11,944,854</b>     | <b>(8,065,624)</b>   |
| <b>Total liabilities, redeemable preferred stock and stockholders' equity (deficit)</b>   | <b>\$ 16,997,489</b>  | <b>\$ 2,654,931</b>  |

*See accompanying notes to unaudited condensed consolidated financial statements.*

**OpGen, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(unaudited)**

|   | Three Months Ended September 30, |                       | Nine Months Ended September 30, |                       |
|---|----------------------------------|-----------------------|---------------------------------|-----------------------|
|   | 2015                             | 2014                  | 2015                            | 2014                  |
| <b>Revenue</b>  |                                  |                       |                                 |                       |
| Product sales   | \$ 929,241                       | \$ 268,854            | \$ 1,432,592                    | \$ 841,567            |
| Laboratory services   | 23,765                           | 88,190                | 87,201                          | 379,339               |
| Collaboration revenue   | 27,780                           | 477,780               | 308,340                         | 1,783,340             |
| <b>Total revenue</b>  | <b>980,786</b>                   | <b>834,824</b>        | <b>1,828,133</b>                | <b>3,004,246</b>      |
| Cost of products sold (excluding depreciation and amortization)       | 562,694                          | 101,425               | 712,016                         | 276,831               |
| Cost of services (excluding depreciation and amortization)            | 46,634                           | 129,120               | 191,738                         | 336,616               |
| <b>Total costs of sales (excluding depreciation and amortization)</b> | <b>609,328</b>                   | <b>230,545</b>        | <b>903,754</b>                  | <b>613,447</b>        |
| <b>Gross profit</b>   | <b>371,458</b>                   | <b>604,279</b>        | <b>924,379</b>                  | <b>2,390,799</b>      |
| <b>Operating expenses</b>   |                                  |                       |                                 |                       |
| Research and development  | 1,724,127                        | 1,029,650             | 3,741,247                       | 3,075,420             |
| General and administrative  | 1,610,828                        | 555,444               | 3,687,313                       | 1,590,085             |
| Sales and marketing   | 979,681                          | 459,064               | 2,815,976                       | 1,486,801             |
| Depreciation and amortization   | 185,177                          | 141,060               | 392,404                         | 461,432               |
| Transaction expenses  | 525,596                          | -                     | 525,596                         | -                     |
| <b>Total operating expenses</b>                                       | <b>5,025,409</b>                 | <b>2,185,218</b>      | <b>11,162,536</b>               | <b>6,613,738</b>      |
| <b>Operating loss</b>   | <b>(4,653,951)</b>               | <b>(1,580,939)</b>    | <b>(10,238,157)</b>             | <b>(4,222,939)</b>    |
| <b>Other income (expense)</b>   |                                  |                       |                                 |                       |
| Interest income   | 2,513                            | 37                    | 9,675                           | 120                   |
| Interest expense  | (17,482)                         | (32,331)              | (1,746,853)                     | (47,468)              |
| Change in fair value of derivative financial instruments and other    | -                                | 4,400                 | (647,342)                       | 4,400                 |
| <b>Total other income (expense)</b>                                   | <b>(14,969)</b>                  | <b>(27,894)</b>       | <b>(2,384,520)</b>              | <b>(42,948)</b>       |
| <b>Loss before income taxes</b>                                       | <b>(4,668,920)</b>               | <b>(1,608,833)</b>    | <b>(12,622,677)</b>             | <b>(4,265,887)</b>    |
| <b>Provision for income taxes</b>                                     | <b>1,662</b>                     | <b>-</b>              | <b>1,662</b>                    | <b>-</b>              |
| <b>Net loss</b>   | <b>(4,670,582)</b>               | <b>(1,608,833)</b>    | <b>(12,624,339)</b>             | <b>(4,265,887)</b>    |
| Preferred stock dividends   | -                                | (175,246)             | (244,508)                       | (458,799)             |
| <b>Net loss available to common stockholders</b>                      | <b>\$ (4,670,582)</b>            | <b>\$ (1,784,079)</b> | <b>\$ (12,868,847)</b>          | <b>\$ (4,724,686)</b> |
| Net loss per common share - basic and diluted                         | <b>\$ (0.38)</b>                 | <b>\$ (4.92)</b>      | <b>\$ (2.00)</b>                | <b>\$ (13.03)</b>     |
| Weighted average shares outstanding - basic and diluted               | 12,261,238                       | 362,537               | 6,444,373                       | 362,537               |
| Net loss  | \$ (4,670,582)                   | \$ (1,608,833)        | \$ (12,624,339)                 | \$ (4,265,887)        |
| Other comprehensive loss - foreign currency translation               | (49)                             | -                     | (49)                            | -                     |
| <b>Comprehensive loss</b>   | <b>\$ (4,670,631)</b>            | <b>\$ (1,608,833)</b> | <b>\$ (12,624,388)</b>          | <b>\$ (4,265,887)</b> |

*See accompanying notes to unaudited condensed consolidated financial statements.*

**OpGen, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
**Nine Months Ended September 30,**  
**(unaudited)**

|   | <b>2015</b>          | <b>2014</b>        |
|---|----------------------|--------------------|
| <b>Cash flows from operating activities</b>                                     |                      |                    |
| Net loss  | \$ (12,624,339)      | \$ (4,265,887)     |
| Adjustments to reconcile net loss to net cash used in operating activities:     |                      |                    |
| Depreciation and amortization   | 392,404              | 461,432            |
| Deferred tax provision  | 1,662                | -                  |
| Noncash interest expense  | 1,598,312            | 20,883             |
| Share-based compensation  | 1,172,231            | 80,457             |
| Inventory obsolescence  | -                    | (44,595)           |
| Change in fair value of derivative financial instruments and other              | 647,342              | (4,400)            |
| Changes in operating assets and liabilities, net of effects of acquisition:     |                      |                    |
| Accounts receivable   | 507,066              | 62,251             |
| Inventory   | 288,126              | (159,174)          |
| All other assets  | (306,386)            | 78,311             |
| Accounts payable  | (814,855)            | 29,853             |
| Accrued compensation and other liabilities                                      | (1,752,790)          | (42,778)           |
| Deferred revenue  | (180,311)            | (121,551)          |
| <b>Net cash used in operating activities</b>                                    | <b>(11,071,538)</b>  | <b>(3,905,198)</b> |
| <b>Cash flows from investing activities</b>                                     |                      |                    |
| Cash acquired in business combination   | 1,367,211            | -                  |
| Purchases of property and equipment   | (89,234)             | (39,537)           |
| <b>Net cash provided by (used in) investing activities</b>                      | <b>1,277,977</b>     | <b>(39,537)</b>    |
| <b>Cash flows from financing activities</b>                                     |                      |                    |
| Proceeds from issuance of common stock, net of issuance costs                   | 4,958,335            | -                  |
| Proceeds from issuance of preferred stock, net of issuance costs                | -                    | 1,937,902          |
| Proceeds from issuance of convertible notes and warrants, net of issuance costs | 1,388,815            | 1,472,386          |
| Proceeds from issuance of promissory notes, net of issuance costs               | 1,741,667            | -                  |
| Proceeds from exercise of stock options and warrants                            | 214                  | -                  |
| Proceeds from initial public offering, net of issuance costs paid in 2015       | 12,408,285           | -                  |
| Payments on debt  | (153,750)            | (3,750)            |
| Payments on capital lease obligations   | (112,200)            | (80,575)           |
| <b>Net cash provided by financing activities</b>                                | <b>20,231,366</b>    | <b>3,325,963</b>   |
| Effects of exchange rates on cash   | (193)                | -                  |
| Net (decrease) increase in cash and cash equivalents                            | 10,437,612           | (618,772)          |
| Cash and cash equivalents at beginning of period                                | 749,517              | 1,400,345          |
| <b>Cash and cash equivalents at end of period</b>                               | <b>\$ 11,187,129</b> | <b>\$ 781,573</b>  |
| <b>Supplemental disclosure of cash flow information</b>                         |                      |                    |
| Cash paid during the period for interest  | \$ 201,233           | \$ 26,088          |
| <b>Supplemental disclosure of noncash investing and financing activities:</b>   |                      |                    |
| Acquisition of equipment purchased through capital leases                       | \$ 429,320           | \$ -               |
| Common stock issued in business combination                                     | \$ 2,584,090         | \$ -               |
| Exchange of demand note for convertible debt                                    | \$ 300,000           | \$ -               |
| Exchange of demand notes for IPO units sold in initial public offering          | \$ 2,100,000         | \$ -               |
| Conversion of convertible notes into Series A preferred stock                   | \$ 3,000,000         | \$ -               |
| Conversion of Series A preferred stock into common shares                       | \$ 8,183,661         | \$ -               |

*See accompanying notes to unaudited condensed consolidated financial statements.*

## Note 1 - Organization

OpGen, Inc. (“OpGen”) was incorporated in Delaware in 2001. On July 14, 2015, OpGen completed the strategic acquisition (the “Merger”) of AdvanDx, Inc. and its wholly owned subsidiary AdvanDx A/S (collectively, “AdvanDx”) (see Note 4). Pursuant to the terms of a merger agreement, Velox Acquisition Corp. (OpGen’s wholly owned subsidiary formed for the express purpose of enacting the Merger) merged with and into AdvanDx, Inc. with AdvanDx, Inc. surviving as OpGen’s wholly owned subsidiary (see Note 4). OpGen, AdvanDx, Inc. and AdvanDx A/S are collectively referred to hereinafter as the “Company.” The Company’s headquarters are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland and Woburn, Massachusetts. The Company also has operations in Copenhagen, Denmark.

OpGen is an early-stage company using rapid molecular testing and bioinformatics to help guide antibiotic therapy and to assist healthcare providers to combat multi-drug resistant infections, or MDROs. OpGen’s lead products are its QuickFISH® and PNAFISH products, which are advanced *in vitro* diagnostic kits for the diagnosis and prevention of infectious diseases, the Acuitas® MDRO Gene Test, a CLIA lab-based test that provides a profile of MDRO resistant genes from patients screened for colonization or infection and the Acuitas Lighthouse to aid in the interpretation of MDRO diagnostic test results. The company develops, markets and sells its products principally for use in hospitals and clinical laboratories in the United States and internationally.

The Company’s operations are subject to certain risks and uncertainties. The risks include rapid technology changes, the need to manage growth, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company’s success depends, in part, on its ability to develop and commercialize its proprietary technology as well as raise additional capital.

## Note 2 – Liquidity and management’s plans

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing arrangements. The Company raised significant funds in 2015, including:

- \$0.8 million in short-term notes (in the first quarter of 2015, \$0.3 million of demand notes held by an entity controlled by our chief executive officer were settled as partial payment for a 2015 convertible note, and in the second quarter of 2015, \$0.2 million of notes from a related party were repaid in cash),
- \$1.5 million through the issuance of convertible notes,
- \$12.1 million in net proceeds from its initial public offering, or IPO, as discussed further below, and
- \$6.0 million in net proceeds from the issuances of common stock and promissory note to Merck Global Health Innovations Fund, LLC (“Merck GHI”).

On May 8, 2015, OpGen completed its IPO pursuant to which it offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds were \$12.1 million. On the IPO closing date, the underwriters exercised their over-allotment option to acquire an additional 422,500 stock purchase warrants. In connection with the IPO, all of OpGen’s outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,852 shares of common stock.

In July 2015, the Company raised \$6.0 million by issuing 1,136,364 shares of common stock (with a value of \$5.0 million at \$4.40 per share) and a \$1.0 million promissory note to Merck GHI (see Note 5).

The Company’s current operating assumptions, which include management’s best estimate of future revenue and operating expenses, indicate that current cash on hand will be sufficient to fund operations through at least the end of the first quarter of 2016. In the event the Company is unable to successfully raise additional capital in 2016, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions. The financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

### **Note 3 - Summary of significant accounting policies**

#### **Basis of presentation and consolidation**

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission, or SEC, for interim financial information. Accordingly, they do not include all the information and footnotes required by U.S. Generally Accepted Accounting Principles, or GAAP, for complete financial statements. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2014 previously filed with the SEC. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements included in the Company's registration statement on Form S-1/A and, in the opinion of management, reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of September 30, 2015 and the results of operations and cash flows for the three and nine months ended September 30, 2015 and 2014. The interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2014 balance sheet included herein was derived from the audited financial statements, but may not include all disclosures including notes required by GAAP for complete financial statements.

The accompanying unaudited interim condensed consolidated financial statements include the accounts of the OpGen and its wholly owned and controlled subsidiaries; all intercompany transactions and balances have been eliminated. The Company operates in one business segment. Certain prior period information has been reclassified to conform to the current period presentation.

#### **Foreign Currency**

AdvanDx A/S is located in Copenhagen, Denmark and uses the Danish Krone as its functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in other comprehensive loss, a component of stockholder's equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive loss at September 30, 2015.

Foreign currency transaction gains and losses, excluding gains and losses on intercompany balances where there is no current intent to settle such amounts in the foreseeable future, are included in the determination of net loss.

Unless otherwise noted, all references to "\$" or "dollar" refer to the United States dollar.

#### **Use of estimates**

In preparing financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, share-based compensation, allowances for doubtful accounts and inventory obsolescence, valuation of derivative financial instruments, beneficial conversion features of convertible debt, deferred tax assets and liabilities and related valuation allowance, and depreciation and amortization and estimated useful lives of long-lived assets, and the recoverability of long-lived assets. Actual results could differ from those estimates.

#### **Fair value of financial instruments**

All current assets and liabilities are carried at cost, which approximates fair value, because of the short-term maturities of those instruments. The carrying value of the Company's debt is reflective of fair value based on instruments with similar terms available to the Company.

#### **Cash and cash equivalents**

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The Company has cash and cash equivalents deposited in financial institutions in which the balances occasionally exceed the federal government agency (FDIC) insured limits of \$250,000. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

#### **Accounts receivable**

The Company's accounts receivable result from revenues earned but not collected from customers. Credit is extended based on an evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are due within 30 to 45 days and are stated at amounts due from customers. The Company evaluates if an allowance is necessary by considering a number of factors, including the length of time accounts receivable are past due, the Company's previous loss history and the customer's current ability to pay its obligation. If amounts become uncollectible, they are charged to operations when that determination is made. The allowance for doubtful accounts was \$79,697 as of September 30, 2015 and December 31, 2014, respectively.



At September 30, 2015, the Company had accounts receivable from two customers which individually represented 12% and 11% of total accounts receivable. At December 31, 2014, the Company had accounts receivable from two customers which individually represented 79%, and 15% of total accounts receivable.

### **Inventories**

Inventories are valued using the first-in, first-out method and stated at the lower of cost or market and consist of the following:

|                            | <u>September 30,</u><br><u>2015</u> | <u>December 31,</u><br><u>2014</u> |
|----------------------------|-------------------------------------|------------------------------------|
| Raw materials and supplies | \$ 697,414                          | \$ 40,749                          |
| Work-in process            | 222,031                             | 135,625                            |
| Finished goods             | 236,043                             | 193,368                            |
| Total                      | <u>\$ 1,155,488</u>                 | <u>\$ 369,742</u>                  |

Inventories include the Argus Whole Genome Mapping Systems, reagents and supplies used for Argus consumable kits, reagents and components for QuickFISH and PNAFISH kit products, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were \$778,944 and \$867,816 at September 30, 2015 and December 31, 2014, respectively.

### **Product warranty**

A warranty reserve is established upon the sale of any Argus System or Whole Genome Mapping product that is covered by warranty based on the estimated cost of replacement parts during the warranty period. Warranty periods are twelve months. The reserve is adjusted during the warranty period to reflect the remaining estimated costs under the warranty. The reserve for warranties was \$2,750 as of September 30, 2015 and December 31, 2014, respectively.

### **Impairment of property and equipment**

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the three and nine months ended September 30, 2015 and 2014, the Company determined that its property and equipment was not impaired.

### **Intangible assets and goodwill**

Intangible assets were acquired as part of the Merger, and consist of definite-lived intangible assets and goodwill.

#### Definite-lived intangible assets

Definite-lived intangible assets include trademarks, developed technology and customer relationships, and are amortized over their useful lives of 10, 7 and 7 years, respectively. Definite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. During the three and nine months ended September 30, 2015 and 2014, the Company determined that its definite-lived intangible assets were not impaired.

#### Goodwill

Goodwill represents the excess of the purchase price for AdvanDx over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is tax deductible in all relevant jurisdictions. As a result of the Merger, the Company recognized goodwill of approximately \$292,000.

The Company will conduct an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value.

#### **Redeemable convertible preferred stock**

All shares of Series A redeemable convertible preferred stock, or Series A Preferred Stock (including those shares issued in connection with the conversion of the 2014 and 2015 convertible debt (see Note 6)), were converted into 7,374,852 shares of common stock in connection with the Company's IPO (see Note 7).

Prior to the IPO, the carrying value of the Series A Preferred Stock was increased by the accretion of related discounts, issuance costs and accrued but unpaid dividends so that the carrying amount would equal the redemption amount at the dates the stock becomes redeemable. At December 31, 2014, the Company had 3,999,864 shares of Series A Preferred Stock, outstanding. The Series A Preferred Stock was redeemable at the option of the holders of 70% of the outstanding shares of Series A Preferred Stock, subject to certain additional requirements. The Company's redeemable convertible preferred stock was classified as temporary equity due to redemption provisions outside of the Company's control.

#### **Revenue recognition**

The Company recognizes revenue primarily from sales of its products and services when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the selling price is fixed or determinable; and collectability is reasonably assured. At times, the Company sells products and services, or performs software development, under multiple-element arrangements with separate units of accounting; in these situations, total consideration is allocated to the identified units of accounting based on their relative selling prices and revenue is then recognized for each unit based on its specific characteristics.

Amounts billed to customers for shipping and handling are included in revenue when the related product or service revenue is recognized. Shipping and handling costs are included in cost of sales.

#### Revenue from sales of the Argus System

When an Argus System is sold without the Genome Builder software, total arrangement consideration is recognized as revenue when the system is delivered to the customer. Ancillary performance obligations, including installation, limited customer training and limited consumables, are considered inconsequential and are combined with the Argus System as one unit of accounting.

When an Argus System is sold with the Genome Builder software in a multiple-element arrangement, total arrangement consideration is allocated to the Argus System and to the Genome Builder software based on their relative selling prices. Selling prices are determined based on sales of similar systems to similar customers and, where no sales have occurred, on management's best estimate of the expected selling price relative to similar products. Revenue related to the Argus System is recognized when it is delivered to the customer; revenue for the Genome Builder software is recognized when it is delivered to the customer.

#### Revenue from sales of AdvanDx diagnostic products

Revenue from sales of AdvanDx diagnostic products typically is recognized when the product is delivered to the customer.

#### Revenue from sales of Genome Builder Software and consumables (on a stand-alone basis)

Revenue is recognized for Genome Builder Software and for consumables, when sold on a standalone basis, upon delivery to the customer.

#### Revenue from extended warranty service contracts

The Company recognizes revenue associated with extended warranty service contracts over the service period in proportion to the costs expected to be incurred over that same period.

#### Revenue from providing laboratory services

The Company recognizes revenue associated with laboratory services contracts when the service has been performed and reports are made available to the customer.

#### Revenue from funded software development arrangements

The Company's funded software development arrangements generally consist of multiple-elements. Total arrangement consideration is allocated to the identified units of accounting based on their relative selling prices and revenue is then recognized for each unit based on its specific characteristics. When funded software development arrangements include substantive research and development milestones, revenue is recognized for each such milestone when the milestone is achieved and is due and collectible. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with achievement of the milestone.

**Share-based compensation**

Share-based payments are recognized at fair value. The fair value of share-based payments to employees and directors is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. For all time-vesting awards granted, expense is amortized using the straight-line attribution method. Share-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period.

Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

**Income taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between 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 be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred income tax assets to the amount expected to be realized. The Company's tax provision for the three and nine months ended September 30, 2015 resulted from the deductibility of goodwill for tax purposes.

Tax benefits are initially recognized in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially, and subsequently, measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts.

The Company had federal net operating loss, or NOL, carryforwards of \$76,267,809 at December 31, 2014. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have future tax liability due to alternative minimum tax or state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. There can be no assurance that the NOL carryforwards will ever be fully utilized.

**Loss per share**

Basic loss per share is computed by dividing net loss available to common shareholders by the weighted average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options and stock purchase warrants using the treasury stock method, and convertible preferred stock and convertible debt using the if-converted method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) restricted stock units (in 2014), (iii) stock purchase warrants, and (iv) prior to the IPO, convertible preferred stock and convertible debt, exercisable or exchangeable into common stock which have been excluded from the computation of diluted loss per share, was 5.7 million and 6.1 million for the nine and three months ended September 30, 2015 and 2014, respectively. The Company's convertible preferred stock, prior to its conversion, contained non-forfeitable rights to dividends, and therefore was considered to be a participating security; the calculation of basic and diluted income (loss) per share excludes net income (but not net loss) attributable to the convertible preferred stock from the numerator and excludes the impact of those shares from the denominator in periods prior to the IPO.

**Recent accounting pronouncements**

In May 2014, the Financial Accounting Standards Board, or FASB, issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. The standard is effective for the Company's reporting year beginning January 1, 2018 and early adoption is permitted starting January 1, 2017. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance 1) provides a definition for the term "substantial doubt," 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The standard is effective for the Company's reporting year beginning January 1, 2017 and early adoption is permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In April 2015, the FASB issued accounting guidance requiring that debt issuance costs related to a recognized liability be presented on the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected. The standard is effective for reporting periods beginning after December 15, 2015. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In July 2015, the FASB issued accounting guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In September 2015, the FASB issued accounting guidance to simplify the accounting for measurement period adjustments resulting from business combinations. Under the guidance, an acquirer will be required to recognize adjustments to provisional amounts identified during the measurement period in the reporting period in which the adjustments are determined. The guidance requires an entity to present separately on the face of the income statement or disclose in the notes to the financial statements the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment had been recognized as of the acquisition date. The standard is effective for reporting periods beginning after December 15, 2015. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

The Company has evaluated all other issued and unadopted Accounting Standards Updates and believes the adoption of these standards will not have a material impact on its results of operations, financial position, or cash flows.

#### **Note 4 – Business Combination**

On July 14, 2015, the Company completed the Merger by acquiring 100% of the capital stock of AdvanDx in the Merger in a taxable transaction. AdvanDx researches, develops and markets advanced *in vitro* diagnostic kits for the diagnosis and prevention of infectious diseases, and sells its products principally to hospitals and clinical laboratories in the United States and Europe. The Company acquired AdvanDx principally to exploit AdvanDx's diagnostic capabilities with respect to MDROs and leverage AdvanDx's relationships with hospitals and clinical laboratories to accelerate the sales of OpGen's products and services.

Pursuant to an Agreement and Plan of Merger (the "Merger Agreement"), Velox Acquisition Corp. merged with and into AdvanDx, Inc. with AdvanDx, Inc. surviving as a wholly owned subsidiary of the Company in accordance with the General Corporation Law of the State of Delaware. Under the terms of the Merger Agreement, the merger consideration consisted of an aggregate 681,818 shares of the Company's common stock with a value of \$2.6 million (the "Merger Consideration"), which Merger Consideration was distributed in accordance with the liquidation preferences set forth in the AdvanDx, Inc. Restated Certificate of Incorporation, as amended.

The Company accounted for its acquisition of AdvanDx by recording all tangible and intangible assets acquired and liabilities assumed at their estimated fair values on the acquisition date, with the remaining unallocated purchase price recorded as goodwill. The fair value assigned to identifiable intangible assets acquired was determined using an income approach for trade names and customer relationships, and a cost approach for technology. The fair values are based on the Company's estimates and may be adjusted from time to time, but no later than July 13, 2016, as better information becomes available. The Company received stepped-up bases in the acquired assets and liabilities and therefore did not recognize any deferred income tax assets and liabilities. The following represents the preliminary allocation of the purchase price:

|  |                     |
|--|---------------------|
| Total purchase price - fair value of common stock issued | \$ 2,584,090        |
| Fair value of tangible assets acquired:                  |                     |
| Cash   | 1,367,211           |
| Receivables  | 557,112             |
| Inventory  | 1,073,855           |
| Property and equipment                                   | 250,636             |
| Other assets   | 359,587             |
| Fair value of identifiable intangible assets acquired:   |                     |
| Customer relationships                                   | 1,094,000           |
| Developed technology                                     | 458,000             |
| Trademarks and tradenames                                | 461,000             |
| Fair value of goodwill                                   | 291,747             |
| Fair value of liabilities assumed                        | 3,329,058           |
|  | <u>\$ 2,584,090</u> |

The total consideration paid in the acquisition exceeded the estimated fair value of the tangible and identifiable intangible assets acquired and liabilities assumed, resulting in approximately \$0.3 million of goodwill. Goodwill, primarily related to expected synergies gained from combining operations, sales growth from future product offerings and customers, together with certain intangible assets that do not qualify for separate recognition, including assembled workforce, is tax deductible in all relevant taxing jurisdictions. The Company expensed acquisition-related costs of approximately \$0.5 million related to the Merger in 2015. AdvanDx recognized approximately \$0.8 million of revenue and \$0.8 million of net losses from the acquisition date to September 30, 2015, which results are included in the Company's 2015 interim condensed consolidated financial statements.

The following unaudited pro forma financial information summarizes the results of operations for the periods indicated as if the Merger had been completed as of January 1, 2014. Pro forma information primarily reflects adjustments relating to (i) elimination of the interest on AdvanDx's outstanding debt, and (ii) the amortization of intangibles acquired. The pro forma amounts do not purport to be indicative of the results that would have actually been obtained if the acquisition occurred as of January 1, 2014 or that may be obtained in the future:

| Unaudited pro forma results | Nine months ended     |                       | Three months ended    |                       |
|-----------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                             | September 30,<br>2015 | September 30,<br>2014 | September 30,<br>2015 | September 30,<br>2014 |
| Revenues                    | \$ 3,902,337          | \$ 6,631,510          | \$ 1,126,530          | \$ 1,955,894          |
| Net loss                    | \$ (15,623,109)       | \$ (11,784,997)       | \$ (4,650,817)        | \$ (4,517,541)        |
| Net loss per share          | \$ (2.29)             | \$ (11.72)            | \$ (0.38)             | \$ (4.49)             |

#### Note 5 – Merck GHI Financing

On July 14, 2015, as a condition to the Merger, the Company entered into a Common Stock and Note Purchase Agreement (the "Purchase Agreement") with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of common stock of the Company at \$4.40 per share for gross proceeds of \$5.0 million. Pursuant to the Purchase Agreement, the Company also issued to Merck GHI a 8% Senior Secured Promissory Note (the "Note") in the principal amount of \$1.0 million with a two-year maturity date from the date of issuance. The Company's obligations under the Note are secured by a lien on all of the Company's assets.

The Company incurred issuance costs of approximately \$50,000 related to the financing, of which approximately \$8,000 was deferred as debt issuance costs and are being amortized as interest expense over the life of the Note, and \$42,000 was charged to additional paid-in capital.

#### Note 6 - Fair value measurements

The Company classifies its financial instruments using a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 - defined as observable inputs such as quoted prices in active markets;
- Level 2 - defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 - defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions such as expected revenue growth and discount factors applied to cash flow projections.

Financial assets and liabilities measured at fair value on a recurring basis

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy. The following tables present the fair value hierarchy for the Company's financial assets and liabilities measured at fair value on a recurring basis at September 30, 2015 and December 31, 2014:

|                           | <b>Fair value at<br/>September 30,</b> |                |                |                |
|---------------------------|--|----------------|----------------|----------------|
|                           | <b>2015</b>                            | <b>Level 1</b> | <b>Level 2</b> | <b>Level 3</b> |
| Cash and cash equivalents | \$ 11,187,129                          | \$ 11,187,129  | \$ -           | \$ -           |

  

|                           | <b>Fair value at<br/>December 31,</b> |                |                |                |
|---------------------------|---------------------------------------|----------------|----------------|----------------|
|                           | <b>2014</b>                           | <b>Level 1</b> | <b>Level 2</b> | <b>Level 3</b> |
| Cash and cash equivalents | \$ 749,517                            | \$ 748,048     | \$ 1,469       | \$ -           |

The Company's Level 1 securities primarily consist of cash and cash equivalents, including money market funds and U.S. Treasury Notes; the Company determines the estimated fair value for its Level 1 securities using quoted (unadjusted) prices for identical assets or liabilities in active markets.

Prior to its IPO, certain stock purchase warrants contained cash settlement features and, accordingly, the Company considered them to be derivative financial instruments and accounted for them at fair value using level 3 inputs. As a result of the Company's IPO and elimination of the cash settlement features pursuant to their terms, those stock purchase warrants were reclassified to equity. For periods prior to the IPO, the Company determined the fair value of these derivative liabilities using a hybrid valuation method that consisted of a probability weighted expected return method that values the Company's equity securities assuming various possible future economic outcomes while using an option pricing method (that treated all equity linked instruments as call options on the Company's equity value with exercise prices based on the liquidation preference of the Series A Preferred Stock ) to estimate the allocation of value within one or more of the scenarios. Using this hybrid method, unobservable inputs included the Company's equity value, the exercise price for each option value, expected timing of possible economic outcomes such as initial public offering, risk free interest rates and stock price volatility. The following tables set forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the nine months ended September 30, 2015:

| <b>Description</b>           | <b>Balance at<br/>December<br/>31, 2014</b> | <b>Established<br/>in 2015</b> | <b>Change in<br/>Fair Value</b> | <b>Reclassified<br/>to Equity</b> | <b>Balance at<br/>September<br/>30, 2015</b> |
|------------------------------|---|--------------------------------|---------------------------------|-----------------------------------|--|
| Derivative warrant liability | \$ -  | \$ 72,333                      | \$ 647,342                      | \$ (719,675)                      | \$ -   |

Financial assets and liabilities carried at fair value on a non-recurring basis

The Company does not have any financial assets and liabilities measured at fair value on a non-recurring basis.

Non-financial assets and liabilities carried at fair value on a recurring basis

The Company does not have any non-financial assets and liabilities measured at fair value on a recurring basis.

Non-financial assets and liabilities carried at fair value on a non-recurring basis

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when they are deemed to be impaired. No such fair value impairment was recognized in the three and nine month periods ended September 30, 2015 and 2014.

See Note 4 for a discussion of the fair value of assets acquired and liabilities assumed in the Merger.

## **Note 7 – Series A redeemable convertible preferred stock**

All shares of Series A Preferred Stock (including those shares issued in connection with the conversion of the 2014 and 2015 convertible debt (see Note 6)) were converted into 7,374,852 shares of common stock in connection with the Company's IPO (see Note 9). Prior to the Company's IPO, the Series A Preferred Stock was classified as temporary equity due to redemption provisions outside of the Company's control.

The Company issued 1,999,864 shares of Series A Preferred Stock in December 2013 at \$1.00 per share in exchange for \$1,999,864 in convertible promissory notes. In February 2014, the Company sold 1,405,096 shares of Series A Preferred Stock for gross proceeds of \$1,405,096. In April 2014, the Company sold an additional 594,904 shares of Series A Preferred Stock for gross proceeds of \$594,904. At December 31, 2014, the Company had a total of 3,999,864 shares of Series A Preferred Stock outstanding, convertible into 3,999,864 shares of common stock.

The holders of the Series A Preferred Stock had the right to receive non-cumulative dividends, at a rate of 8% per annum, when and if declared by the Board of Directors. The Series A Preferred Stock had preference of payment over all other classes and series of capital stock of the Company with respect to dividends, payment on liquidation and payment on redemption. The liquidation and redemption preferences were at two times the Series A Preferred Stock purchase price. The Series A Preferred Stock holders were entitled to vote on all matters that come to stockholders on an as-converted basis with holders of the common stock. In addition, the Series A Preferred Stock had broad based anti-dilution rights.

The holders of Series A Preferred Stock had the right to convert such shares, at their option and at any time, into shares of common stock at the then-applicable conversion rate, as defined. The initial conversion rate was one common share for each preferred share, which could be adjusted for specified dilutive transactions. Beginning in December 2020, the Company may have been obligated to redeem shares of Series A Preferred Stock, if requested, by holders of at least 70% of the then-outstanding shares of preferred stock. The redemption, if requested, would have taken place in three equal annual installments. Series A Preferred Stock would have been redeemed at two times the original issue price per share plus all accrued and unpaid dividends. The redemptions were subject to certain equity adjustments for specified anti-dilution transactions, as defined.

## **Note 8 - Debt**

All the Company's outstanding demand notes and convertible notes were exchanged for units in the Company's IPO or otherwise were converted into Series A Preferred Stock and subsequently converted into shares of common stock in connection with the IPO. A short-term 8% promissory note for \$150,000 issued in April 2015 was repaid in cash in June 2015. In July 2015, the Company issued a \$1.0 million 8% senior secured promissory note to Merck GHI (see Note 5). As of September 30, 2015, the Company has a total of \$1,001,250 debt outstanding.

### **Demand notes**

In the fourth quarter of 2014 and first quarter of 2015, the Company raised a total of \$2.3 million through the issuance of short-term demand notes. In the first quarter of 2015, \$0.3 million of demand notes, held by an entity controlled by our chief executive officer, were settled as partial payment for a 2015 convertible note. All outstanding demand notes were tendered as payment for 350,000 units in the Company's IPO (see Note 9). Prior to settlement, the demand notes bore interest at 8% per annum, had a first priority security interest in the assets of the Company, and a term of approximately four months.

### **2014 convertible debt**

In July, August and September 2014, the Company raised \$1.5 million through the issuance of convertible debt. All outstanding 2014 convertible debt was converted into Series A Preferred Stock and then into 1,500,000 shares of common stock in connection with the Company's IPO (see Note 9). Prior to its conversion, the debt was convertible, at the option of the holders or in certain cases at the Company's option, into shares of Series A Preferred Stock or other potential equity securities, bore interest at 8% and was due in full on July 11, 2015.

### **2015 convertible debt**

In February and March 2015, the Company raised \$1.5 million in capital through the issuance of 8% secured convertible notes with detachable stock purchase warrants. All outstanding 2015 convertible debt was converted into Series A Preferred Stock and then into 1,875,000 shares of common stock in connection with the Company's IPO (see Note 9). Prior to its conversion, the 2015 convertible notes were pre-payable by the Company without penalty at any time following the three-month anniversary of the closing of the IPO (provided that before the six-month anniversary of the closing of an IPO, the 2015 convertible notes could only be prepaid out of newly issued capital subsequent to the IPO), and were puttable by the holder to the Company in the event of a defined default. The 2015 convertible notes were each convertible, at the election of the holder, into (i) shares of Series A Preferred Stock, at a conversion rate of 1.25 shares of Series A Preferred Stock for each \$1.00 converted if the conversion occurs prior to closing of an IPO, or (ii) shares of common stock at a conversion rate of one share of common stock for each \$1.00 converted if the conversion occurs after the closing of an IPO.

The conversion option embedded in the convertible notes was determined to contain beneficial conversion features, resulting in the bifurcation of those features as an equity instrument (resulting in an additional debt discount) at issuance. After allocation of the gross proceeds to the detachable stock purchase warrants (discussed below) and beneficial conversion feature, the total debt discount recognized was equal to the face value of the 2015 convertible notes. Upon conversion in May 2015, the remaining unamortized beneficial conversion feature of approximately \$1.5 million was charged to interest expense in the accompanying condensed consolidated statement of operations. Remaining unamortized deferred financing costs of \$71,421 were also charged to interest expense upon conversion.

The 2015 convertible note holders also received detachable stock purchase warrants exercisable for 225,011 shares of common stock at 110% of the IPO price and exercisable only if the IPO occurred, and then exercisable beginning on the six-month anniversary of the closing of the IPO. Prior to the IPO, as a result of net settlement features, the stock purchase warrants were considered derivative liabilities, were initially recorded at fair value (resulting in a debt discount) and were marked-to-market at each balance sheet date through earnings. As a result of the elimination of the net settlement features in the IPO, the stock purchase warrants were marked to fair value of \$0.7 million on May 8, 2015 and then reclassified to equity.

#### **Note 9 - Stockholders' equity (deficit)**

On May 8, 2015, the Company completed its IPO pursuant to which the Company offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, and underwriting discounts, commissions and offering expenses of \$2.9 million (which were charged to additional paid in capital), the total net cash proceeds to the Company was \$12.1 million. On the IPO closing date, the underwriters exercised a portion of their over-allotment option to acquire an additional 422,500 stock purchase warrants for cash of \$4,225. In connection with the IPO, all of the Company's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,852 shares of common stock.

The stock purchase warrants issued as part of the units (including over-allotment option) are exercisable for 3,272,500 shares of common stock at \$6.60 per share beginning six months after the closing of the IPO for five years, expiring on May 8, 2020. Additionally, the Company issued additional warrants to its investment bankers to purchase 185,250 shares of common stock, on the same terms as the warrants issued with the units. The warrants were valued using the Black-Scholes option pricing model and are classified as equity.

In July 2015, the Company issued 1,136,364 shares of common stock to Merck GHI for cash consideration of \$5.0 million (see Note 5).

#### **Stock options**

In 2002, the Company adopted the 2002 Stock Option and Restricted Stock Plan, or the 2002 Plan, pursuant to which the Company's Board of Directors could grant either incentive stock options or non-qualified stock options, shares of restricted stock, shares of unrestricted common stock, and other share-based awards to officers and employees. In 2008, the Company adopted the 2008 Stock Option and Restricted Stock Plan, or the 2008 Plan, pursuant to which the Company's Board of Directors may grant either incentive or non-qualified stock options or shares of restricted stock to directors, key employees, consultants and advisors.

In April 2015, the Company adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan, or the 2015 Plan; the 2015 Plan became effective upon the execution and delivery of the underwriting agreement for the Company's IPO. Following the effectiveness of the 2015 Plan, no further grants will be made under the 2002 Plan or 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Internal Revenue Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 1,355,000 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Board of Directors. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of September 30, 2015, 528,890 shares remain available for issuance under the 2015 Plan.



For the three months ended September 30, 2015 and 2014, the Company recorded \$261,540 and \$24,977, respectively, of stock compensation expense. For the nine months ended September 30, 2015 and 2014, the Company recorded \$1,172,231 and \$80,457, respectively, of stock compensation expense. The allocation of share-based compensation expense by operating expenses is as follows:

|                            | <b>Three months ended September 30,</b> |                  |
|----------------------------|---|------------------|
|                            | <b>2015</b>                             | <b>2014</b>      |
| Research and development   | \$ 59,688                               | \$ 1,528         |
| General and administrative | 156,236                                 | 22,460           |
| Sales and marketing        | 45,616                                  | 989              |
|                            | <u>\$ 261,540</u>                       | <u>\$ 24,977</u> |

  

|                            | <b>Nine months ended September 30,</b> |                  |
|----------------------------|--|------------------|
|                            | <b>2015</b>                            | <b>2014</b>      |
| Research and development   | \$ 161,819                             | \$ 3,903         |
| General and administrative | 443,267                                | 74,032           |
| Sales and marketing        | 567,145                                | 2,522            |
|                            | <u>\$ 1,172,231</u>                    | <u>\$ 80,457</u> |

During the nine months ended September 30, 2015, the Company granted stock options to acquire 1,660,387 shares of common stock at a weighted average exercise price of \$2.87 per share. The 2015 awards had a weighted average grant date fair value per share of \$3.16. The Company has total stock options to acquire 1,948,249 shares of common stock outstanding at September 30, 2015.

#### **Restricted stock units**

In March 2014, the Company awarded restricted stock units to acquire 130,640 shares of common stock to its Chief Executive Officer. The restricted stock units were compensation for his service as Chief Executive Officer, or CEO, from October 2013 through June 2014 and were subject to forfeiture if he did not continue to perform management services through October 24, 2014. The restricted stock units vested on October 24, 2014 and 130,640 shares of common stock were issued to the CEO.

#### **Stock purchase warrants**

The Company has total stock purchase warrants to acquire 3,716,355 and 33,594 shares of common stock outstanding at September 30, 2015 and December 31, 2014, respectively. In the first quarter of 2015, the Company issued 225,011 warrants in connection with the issuance of its 2015 convertible debt. In the second quarter of 2015 in connection with the Company's IPO, the Company issued 3,457,750 stock purchase warrants to investors and to its investment bankers. As of September 30, 2015, the warrants are classified as equity.

#### **Note 10 - Commitments and contingencies**

##### **Operating leases**

During the second quarter 2015, the Company extended the term of its Gaithersburg, Maryland office lease, effective May 7, 2015, through January 31, 2021, with one additional five-year renewal at the Company's election. The Company is responsible for all utilities, repairs, insurance, and taxes under this operating lease. Effective July 1, 2015, the Company further modified its lease agreement to add additional leased space to its headquarters. The Company also leases a facility in Woburn, Massachusetts under an operating lease that expires in January 2016, and provides the Company with options to extend the lease beyond the current expiration date. Additionally, the Company leases office space in Denmark; this lease was extended in September 2015 and is currently on a month-to-month basis. Rent expense under the Company's facility operating leases for the nine months ended September 30, 2015 and 2014 was \$447,007 and \$341,862, respectively.

##### **Capital leases**

The Company leases computer equipment, office furniture, and equipment under various capital leases. The leases expire at various dates through 2018. The leases require monthly principal and interest payments.

**Registration and other shareholder rights**

In connection with the Merger and the investment transactions (see Notes 4 and 5), the Company also entered into a Registration Rights Agreement with the AdvanDx stockholders receiving Merger Consideration and with Merck GHI, pursuant to which the investors were granted certain demand registration rights and piggyback registration rights in connection with subsequent registered offerings of the Company's common stock. Merck GHI also received rights to participate on a pro-rata basis in future securities offerings by the Company.

On December 18, 2013, the Company entered into the Third Amended and Restated Investors' Rights Agreement (the "Investors' Rights Agreement") with investors acquiring promissory notes convertible into shares of the Company's Series A Preferred Stock. Following the IPO, the holders of 20% or more of the securities subject to the Investors' Rights Agreement have demand registration rights and piggyback registration rights in connection with subsequent registered offerings of the Company's common stock.

**Note 11 - License agreements, research collaborations and development agreements**

OpGen is a party to two license agreements to acquire certain patent rights and technologies. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. Certain of the agreements require the Company to pay minimum royalties or license maintenance fees. The Company recognized \$7,484 and \$23,810 of net royalty expense for the three months ended September 30, 2015 and 2014, respectively and (\$13,769) and \$73,142 of net royalty (income) expense for the nine months ended September 30, 2015 and 2014, respectively. In 2015, future minimum royalty fees are \$20,000 under these agreements.

In September 2013, OpGen entered into a technology development agreement in which the Company would receive fixed milestone payments for meeting development milestones under the agreement. Since the milestones are substantive, the Company recognizes revenue in the periods in which the substantive milestones are achieved; the Company attained sixteen milestones during 2014. In addition, the Company received an upfront payment of \$250,000, which is recognized on a straight-line basis over the term of the technology development agreement. The Company recognized total revenue of \$208,340 and \$1,133,340 during the nine months ended September 30, 2015 and 2014, respectively, and \$27,780 and \$172,220 during the three months ended September 30, 2015 and 2014, respectively, relating to this arrangement.

In July 2003, AdvanDx entered into a non-exclusive, non-sublicensable, worldwide license agreement with Life Technologies, Inc. ("Life Technologies") to use certain patent rights that allow it to manufacture and sell certain products. The agreement was amended multiple times through 2009 to add additional features and modify certain terms and conditions. Life Technologies is entitled to certain royalties on product sales. The Company expensed royalties of \$150,570 since the Merger.

**Note 12 - Related party transactions**

In March 2014, the Company entered into a supply agreement with Fluidigm Corporation, or Fluidigm, under which Fluidigm supplies the Company with its microfluidic test platform for use in manufacturing the Acuitas MDRO Gene Test. The Company's CEO and Chairman of the Board of Directors of the Company, is a director of Fluidigm.

On July 12, 2015, the Company entered into a letter agreement, or the Agreement, with Fluidigm to expand the companies' existing relationship to include collaborating on the development of test kits and custom analytic instruments for identification, screening and surveillance testing of MDROs. The Agreement also expands the existing Supply Agreement between the Company and Fluidigm, and provides for expansion of the gene targets and organisms to be tested on the Company's existing CLIA lab-based tests, the Acuitas MDRO Gene Test and the Acuitas Resistome Test, using Fluidigm technologies and products. Additionally, Fluidigm has agreed not to develop or directly collaborate with any third party to develop an FDA approved or CE marked diagnostic tests for the purpose of detecting resistome genes for identified MDROs if the Company meets certain minimum purchase commitments and other requirements. The initial term of the Agreement is five years. Both parties have the ability to extend the term for an additional five years. Under the expanded Supply Agreement, the term is extended until March 17, 2018, and the Company has the right to extend the term of the Supply Agreement for up to two additional three-year terms.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited condensed financial statements and the accompanying notes thereto included in Part I, Item 1 of this quarterly report on Form 10-Q. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under Part II, Item 1A, "Risk Factors" as well as our Form 10-Q for the periods ended March 31, 2015 and June 30, 2015 filed with the SEC.

### Overview

OpGen is an early-stage company using rapid molecular testing and bioinformatics to help guide antibiotic therapy and to assist healthcare providers to combat multi-drug resistant infections, or MDROs. OpGen's lead products are its QuickFISH® and PNAFISH products, which are advanced *in vitro* diagnostic kits for the diagnosis and prevention of infectious diseases, the Acuitas® MDRO Gene Test, a CLIA lab-based test that provides a profile of MDRO resistant genes from patients screened for colonization or infection and the Acuitas Lighthouse to aid in the interpretation of MDRO diagnostic test results. The company develops, markets and sells its products principally for use in hospitals and clinical laboratories in the United States and internationally.

On July 14, 2015, OpGen completed the strategic acquisition (the "Merger") of AdvanDx, Inc. and its wholly owned subsidiary AdvanDx A/S (collectively, "AdvanDx"). AdvanDx researches, develops and markets advanced *in vitro* diagnostic kits for the diagnosis and prevention of infectious diseases, and sells its products principally to hospitals and clinical laboratories in the United States and Europe. The Company acquired AdvanDx principally to exploit AdvanDx's diagnostic capabilities with respect to MDROs and leverage AdvanDx's relationships with hospitals and clinical laboratories to accelerate the sales of OpGen's products and services.

The Company's headquarters are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland and Woburn, Massachusetts. The Company also has operations in Copenhagen, Denmark. The Company operates in one business segment.

### Recent Developments

Since inception, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing arrangements. The Company raised significant funds in 2015, including:

- \$0.8 million in short-term notes (in the first quarter of 2015, \$0.3 million of demand notes held by an entity controlled by our chief executive officer were settled as partial payment for a 2015 convertible note, and in the second quarter of 2015, \$0.2 million of notes from a related party were repaid in cash),
- \$1.5 million through the issuance of convertible notes,
- \$12.1 million in net proceeds from its initial public offering, or IPO, as discussed further below, and
- \$6.0 million in net proceeds from the issuances of common stock and promissory note to Merck Global Health Innovations Fund, LLC ("Merck GHI").

On May 8, 2015, OpGen completed its IPO pursuant to which it offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds were \$12.1 million. On the IPO closing date, the underwriters exercised their over-allotment option to acquire an additional 422,500 stock purchase warrants. In connection with the IPO, all of OpGen's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,852 shares of common stock.

On July 14, 2015, the Company completed the strategic acquisition of AdvanDx. Pursuant to the Merger Agreement, a newly formed Merger Sub merged with and into AdvanDx, with AdvanDx surviving as a wholly owned subsidiary of the Company in accordance with the General Corporation Law of the State of Delaware. Under the terms of the Merger Agreement, the Merger Consideration consisted of an aggregate 681,818 shares of the Company's common stock with a value of \$2.6 million (based on the closing sales price of our common stock of \$3.79 per share on July 13, 2015).

In July 2015, the Company raised \$6.0 million by issuing 1,136,364 shares of common stock (with a value of \$5.0 million at \$4.40 per share) and a \$1.0 million promissory note to Merck GHI.

On July 14, 2015, the Company entered into a Registration Rights Agreement with Merck GHI and the AdvanDx stockholders who received Merger Consideration in the Merger, which will require the Company to register such shares of Company common stock for resale by such holders in the future. Under the Purchase Agreement, Merck GHI has the right to participate in future securities offerings made by the Company. There is no assurance that Merck GHI will exercise such participation rights in the future.

The Company's current operating assumptions, which include management's best estimate of future revenue and operating expenses, indicate that current cash on hand will be sufficient to fund operations through at least the end of the first quarter of 2016. In the event the Company is unable to successfully raise additional capital in 2016, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions. The condensed consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

#### Results of operations for the nine months ended September 30, 2015 and 2014

##### Revenues and gross profit

|                       | Nine months ended September 30, |                     |
|-----------------------|---------------------------------|---------------------|
|                       | 2015                            | 2014                |
| <i>Revenue</i>        |                                 |                     |
| Product sales         | \$ 1,432,592                    | \$ 841,567          |
| Laboratory services   | 87,201                          | 379,339             |
| Collaboration revenue | 308,340                         | 1,783,340           |
| Total revenue         | <u>1,828,133</u>                | <u>3,004,246</u>    |
| <i>Cost of sales</i>  |                                 |                     |
| Cost of products sold | 712,016                         | 276,831             |
| Cost of services      | 191,738                         | 336,616             |
| Total cost of sales   | <u>903,754</u>                  | <u>613,447</u>      |
| Gross Profit          | <u>\$ 924,379</u>               | <u>\$ 2,390,799</u> |

Our total revenue for the nine months ended September 30, 2015 decreased 39%, to \$1.8 million from \$3.0 million, when compared to the same period in 2014. This decrease is primarily attributable to:

- Product Sales: an increase in revenue of 70% in 2015 as compared to 2014 is attributable to the inclusion of AdvanDx products sales subsequent to the Merger, offset in part by a reduction in the sale of our Argus products, as we transition from our legacy mapping products to the introduction of Acuitas MDRO products;
- Laboratory Services: a decrease in revenue of 77% in 2015 as compared to 2014 as a result of a reduction in sales of mapping products, as we transition from our legacy mapping products to the introduction of Acuitas MDRO products; and
- Collaborative Revenue: a decrease in revenue generated under a certain collaborative arrangement of 83% in 2015 as compared to 2014 as a result of nearing completion of a technology development agreement.

The Company expects revenues for the year ending December 31, 2015 to remain below 2014 levels as a result of a strategic shift from Argus and Whole Genome Mapping product sales and collaborations to a focus on its QuickFISH and PNAFISH diagnostic products, Acuitas MDRO test products and Acuitas Lighthouse Management System products and services.

Gross profit for the nine months ended September 30, 2015 decreased 61%, to \$0.9 million from \$2.4 million, when compared to the same period in 2014. This decrease is primarily attributable to the inclusion of AdvanDx cost of sales subsequent to the Merger, along with a decrease in the cost of generating collaboration revenue.

## Operating expenses

|                               | <u>2015</u>          | <u>2014</u>         |
|-------------------------------|----------------------|---------------------|
| Research and development      | \$ 3,741,247         | \$ 3,075,420        |
| General and administrative    | 3,687,313            | 1,590,085           |
| Sales and marketing           | 2,815,976            | 1,486,801           |
| Depreciation and amortization | 392,404              | 461,432             |
| Transaction expenses          | 525,596              | -                   |
| Total operating expenses      | <u>\$ 11,162,536</u> | <u>\$ 6,613,738</u> |

The Company's total operating expenses for the nine months ended September 30, 2015 increased 69%, to \$11.2 million from \$6.6 million, when compared to the same period in 2014. This increase is primarily attributable to:

- Research and Development: an increase in expenses of \$0.7 million primarily due to the inclusion of \$0.7 million of AdvanDx expenses subsequent to the Merger;
- General and Administrative: an increase in expenses of \$2.1 million primarily due the inclusion of \$0.3 million of AdvanDx expenses subsequent to the Merger, salaries of \$0.5 million, public company costs of \$0.8 million and share-based compensation costs of \$0.4 million;
- Sales and Marketing: an increase in expenses of \$1.3 million primarily due to the inclusion of \$0.3 million of AdvanDx expenses subsequent to the Merger, clinical outcome cost benefit studies costs of \$0.6 million, and share-based compensation costs of \$0.6 million;
- Depreciation and Amortization: a decrease in expenses due to higher depreciation in the first half of 2014, offset in part by additional amortization expense related to intangible assets recognized subsequent to the Merger; and
- Transaction Expenses: the Company incurred \$0.5 million of transaction expenses in connection with the Merger.

## Other income (expense)

|  | <b>Nine months ended September 30,</b> |                    |
|--|--|--------------------|
|  | <u>2015</u>                            | <u>2014</u>        |
| Interest income  | \$ 9,675                               | \$ 120             |
| Interest expense   | (1,746,853)                            | (47,468)           |
| Change in fair value of derivative financial instruments and other | (647,342)                              | 4,400              |
| Total other income (expense)                                       | <u>\$ (2,384,520)</u>                  | <u>\$ (42,948)</u> |

Other income (expense) for the nine months ended September 30, 2015 increased to a net expense of \$2.4 million from a net expense of \$42,948 in 2014, and was primarily the result of \$1.5 million of non-cash interest expense related to the conversion of our convertible notes in May 2015 and the final mark-to-market adjustment related to our warrant liabilities, which were reclassified to stockholders' equity on May 8, 2015 when their net cash-settlement features lapsed.

## Results of operations for the three months ended September 30, 2015 and 2014

### Revenues and gross profit

|                       | <b>Three months ended September 30,</b> |                   |
|-----------------------|---|-------------------|
|                       | <u>2015</u>                             | <u>2014</u>       |
| <i>Revenue</i>        |   |                   |
| Product sales         | \$ 929,241                              | \$ 268,854        |
| Laboratory services   | 23,765                                  | 88,190            |
| Collaboration revenue | 27,780                                  | 477,780           |
| Total revenue         | <u>980,786</u>                          | <u>834,824</u>    |
| <i>Cost of sales</i>  |   |                   |
| Cost of product sales | 562,694                                 | 101,425           |
| Cost of services      | 46,634                                  | 129,120           |
| Total cost of sales   | <u>609,328</u>                          | <u>230,545</u>    |
| Gross Profit          | <u>\$ 371,458</u>                       | <u>\$ 604,279</u> |

Our total revenue for the three months ended September 30, 2015 increased 17%, to \$1.0 million from \$0.8 million, when compared to the same period in 2014. This increase is primarily attributable to:

- Product Sales: an increase in revenue of 245% in 2015 as compared to 2014 was primarily due the inclusion of AdvanDx subsequent to the Merger;
- Laboratory Services: a decrease in revenue of 73% in 2015 as compared to 2014 as a result of a reduction in sales of mapping products, as we transition from our legacy mapping products to the introduction of Acuitas MDRO products; and
- Collaborative Revenue: a decrease in revenue generated under certain Collaborative Arrangements of 94% in 2015 as compared to 2014 as a result of nearing completion of a technology development agreement.

The Company expects revenues for the year ending December 31, 2015 to remain below 2014 levels as a result of a strategic shift from Argus and Whole Genome Mapping product sales and collaborations to a focus on its QuickFISH and PNAFISH diagnostic products, Acuitas MDRO test products and Acuitas Lighthouse Management System products and services.

Gross profit for the three months ended September 30, 2015 decreased 39%, to \$0.4 million from \$0.6 million, when compared to the same period in 2014. This decrease is primarily attributable to the inclusion of AdvanDx cost of sales subsequent to the Merger.

#### **Operating expenses**

|                               | <b>Three months ended September 30,</b> |                     |
|-------------------------------|---|---------------------|
|                               | <b>2015</b>                             | <b>2014</b>         |
| Research and development      | \$ 1,724,127                            | \$ 1,029,650        |
| General and administrative    | 1,610,828                               | 555,444             |
| Sales and marketing           | 979,681                                 | 459,064             |
| Depreciation and amortization | 185,177                                 | 141,060             |
| Transaction expenses          | 525,596                                 | -                   |
| Total operating expenses      | <u>\$ 5,025,409</u>                     | <u>\$ 2,185,218</u> |

The Company's total operating expenses for the three months ended September 30, 2015 increased 130%, to \$5.0 million from \$2.2 million, when compared to the same period in 2014. This increase is primarily attributable to:

- Research and Development: an increase in expenses of \$0.7 million primarily due to the inclusion of \$0.7 million of AdvanDx expenses subsequent to the Merger;
- General and Administrative: an increase in expenses of \$1.1 million primarily due to the inclusion of \$0.3 million of AdvanDx expenses subsequent to the Merger, salary expenses of \$0.2 million, public company costs of \$0.3 million and share-based compensation costs of \$0.2 million;
- Sales and Marketing: an increase in expenses of \$0.5 million primarily due to the inclusion of \$0.3 million of AdvanDx expenses subsequent to the Merger, and \$0.2 million for clinical outcome cost benefit studies;
- Depreciation and Amortization: an increase in expenses due to amortization of intangible assets recognized subsequent to the Merger; and
- Transaction Expenses: the Company incurred \$0.5 million of transaction expenses in connection with the Merger.

#### **Other income (expense)**

|  | <b>Three months ended September 30,</b> |                    |
|--|---|--------------------|
|  | <b>2015</b>                             | <b>2014</b>        |
| Interest income  | \$ 2,513                                | \$ 37              |
| Interest expense   | (17,482)                                | (32,331)           |
| Change in fair value of derivative financial instruments | -                                       | 4,400              |
| Total other income (expense)                             | <u>\$ (14,969)</u>                      | <u>\$ (27,894)</u> |

Other income (expense) for the three months ended September 30, 2015 decreased to a net expense of \$14,969 from a net expense of \$27,894 in 2014.

## Liquidity and capital resources

At September 30, 2015, the Company had cash and cash equivalents of \$11,187,129, compared to \$749,517 at December 31, 2014.

The Company raised significant funds in the first nine months of 2015, including:

- \$0.8 million in short-term notes (in the first quarter of 2015, \$0.3 million of demand notes held by an entity controlled by our chief executive officer were settled as partial payment for a 2015 convertible note, and in the second quarter of 2015, \$0.2 million of notes from a related party were repaid in cash),
- \$1.5 million through the issuance of convertible notes,
- \$12.1 million in net proceeds from its IPO, as discussed further below, and
- \$6.0 million in net proceeds from the issuances of common stock and promissory note to Merck GHI.

In May 2015, the Company completed its IPO pursuant to which the Company offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was \$12.1 million. In connection with the IPO, all of the Company's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,852 shares of common stock.

In July 2015, the Company raised \$6.0 million by issuing 1,136,364 shares of common stock (with a value of \$5.0 million at \$4.40 per share) and a \$1.0 million promissory note to Merck GHI.

The Company's primary cash requirements are to fund operations as well as research and development programs and collaborations, including those related to AdvanDx acquired in July 2015, and to support general and administrative activities, and to fund acquisitions of products or businesses. The Company's current operating assumptions, after the IPO and July acquisition of AdvanDx and the funding provided by Merck GHI, which include management's best estimate of future revenue and operating expenses, indicate that current cash on hand will be sufficient to fund operations through at least the end of the first quarter of 2016. The Company does not currently have any bank credit lines. In the event the Company is unable to successfully raise additional capital in 2016, the Company may not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions.

### Sources and uses of cash

The following table summarizes the net cash and cash equivalents provided by (used in) operating activities, investing activities and financing activities for the periods indicated:

|   | Nine months ended September 30, |                |
|---|---------------------------------|----------------|
|   | 2015                            | 2014           |
| Net cash used in operating activities               | \$ (11,071,538)                 | \$ (3,905,198) |
| Net cash provided by (used in) investing activities | 1,277,977                       | (39,537)       |
| Net cash provided by financing activities           | 20,231,366                      | 3,325,963      |

#### Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2015 consists primarily of our net loss of (\$12.6 million), reduced by certain non-cash items, including depreciation and amortization expense of \$0.4 million, share-based compensation expense of \$1.2 million, change in the fair value of our warrant liability of \$0.6 million, non-cash interest expense including that associated with the conversion of our convertible notes in May 2015 of \$1.5 million, and the net change in operating assets and liabilities of (\$2.3 million). Net cash used in operating activities for the nine months ended September 30, 2014 consists primarily of our net loss of (\$4.3 million), reduced by certain non-cash items, including depreciation and amortization expense of \$0.5 million and share-based compensation expense of \$0.1 million.

#### *Net cash provided by (used in) investing activities*

Net cash provided by (used in) investing activities in 2015 included cash on hand at AdvanDx at the date of the Merger, along with the purchase of property and equipment. Net cash used in investing activities in 2014 included solely the purchase of property and equipment.

#### *Net cash provided by financing activities*

Net cash provided by financing activities for the nine months ended September 30, 2015 of \$20.2 million consisted primarily of net proceeds from the issuance of debt instruments of \$3.1 million, net proceeds from our IPO of \$12.1 million, and the net proceeds from the issuance of common stock of Merck GHI of \$5.0 million. Net cash provided by financing activities for the nine months ended September 30, 2014 of \$3.4 million consisted primarily of net proceeds from the issuance of preferred stock and convertible notes.

#### **Critical accounting policies and use of estimates**

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our unaudited condensed financial statements, estimates are used for, but not limited to, share-based compensation, allowances for doubtful accounts and inventories, valuation of derivative financial instruments, deferred tax assets and liabilities and related valuation allowance, and depreciation and amortization and estimated useful lives of long-lived assets. Actual results could differ from those estimates.

A summary of our significant accounting policies is included in Note 3 to the accompanying unaudited condensed consolidated financial statements. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain.

#### **Revenue Recognition**

The Company recognizes revenue primarily from sales of the Argus System, sales of extended warranty service contracts for the Argus System, sales of AdvanDx diagnostic products, providing laboratory services, and from "funded software development" arrangements with collaborative parties. Revenue is recognized when the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the selling price is fixed or determinable; and collectability is reasonably assured. At times, the Company sells products and services, or performs software development, under multiple-element arrangements with separate units of accounting; in these situations, total consideration is allocated to the identified units of accounting based on their relative selling prices and revenue is then recognized for each unit based on its specific characteristics.

When an Argus System is sold without the Genome Builder software, total arrangement consideration is recognized as revenue when the System is delivered to the customer. Ancillary performance obligations, including installation, limited customer training and limited consumables, are considered inconsequential and are combined with the Argus System as one unit of accounting. When an Argus System is sold with the Genome Builder software in a multiple-element arrangement, total arrangement consideration is allocated to the Argus System and to the Genome Builder software (considered multiple elements) based on their relative selling prices. Selling prices are determined based on sales of similar systems to similar customers and, where no sales have occurred, on management's best estimate of the expected selling price relative to similar products. Revenue related to the Argus System is recognized when it is delivered to the customer; revenue for the Genome Builder software is recognized when it is delivered to the customer. Revenue is recognized for Genome Builder software and for consumables, when sold on a stand-alone basis, upon delivery to the customer.

Revenue for the sales of AdvanDx's diagnostic products typically is recognized when the product is delivered to the customer.

The Company recognizes revenue associated with laboratory services contracts when the service has been performed and reports are made available to the customer.

The Company recognizes revenue associated with extended warranty service contracts over the service period in proportion to the costs expected to be incurred over that same period. The Company's funded software development arrangements generally consist of multiple elements. Total arrangement consideration is allocated to the identified units of accounting based on their relative selling prices and revenue is then recognized for each unit based on its specific characteristics. When funded software development arrangements include substantive research and development milestones, revenue is recognized for each such milestone when the milestone is achieved and is due and collectible. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with achievement of the milestone.



**Impairment of Long-Lived Assets**

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets.

Definite-lived intangible assets include trademarks, developed technology and customer relationships. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any.

Goodwill represents the excess of the purchase price for AdvanDx over the fair values of the acquired tangible or intangible assets and assumed liabilities. The Company will conduct an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value.

**Derivative Financial Instruments**

The Company accounts for its derivative financial instruments, consisting solely of certain stock purchase warrants that contain non-standard anti-dilution provisions and/or cash settlement features, at fair value using level 3 inputs. Fair value of these derivative liabilities is determined using a hybrid valuation method that consists of a probability weighted expected return method that values the Company's equity securities assuming various possible future economic outcomes while using an option pricing method (that treats all equity linked instruments as call options on the Company's equity value with exercise prices based on the liquidation preference of the Series A Preferred Stock) to estimate the allocation of value within one or more of the scenarios. Using this hybrid method, unobservable inputs included the Company's equity value, the exercise price for each option value, expected timing of possible economic outcomes such as initial public offering, risk free interest rates and stock price volatility. The Company's sole derivative financial instrument, a warrant liability, was reclassified to equity in May 2015 as its net-cash settlement features lapsed.

**Share-Based Compensation**

Share-based payments to employees, directors and consultants are recognized at fair value. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. The estimated fair value of equity instruments issued to nonemployees is recorded at fair value on the earlier of the performance commitment date or the date the services required are completed.

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Share-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. The fair value of share-based payments is estimated, on the date of grant, using the Black-Scholes model. Option valuation models, including the Black-Scholes model, require the input of highly subjective estimates and assumptions, and changes in those estimates and assumptions can materially affect the grant-date fair value of an award. These assumptions include the fair value of the underlying and the expected life of the award.

See additional discussion of the use of estimates relating to share-based compensation, and a discussion of management's methodology for developing each of the assumptions used in such estimates, in Note 3 to the accompanying unaudited condensed consolidated financial statements.

**Recently issued accounting pronouncements**

In May 2014, the Financial Accounting Standards Board, or FASB, issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. The standard is effective for the Company's reporting year beginning January 1, 2018 and early adoption is permitted starting January 1, 2017. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance 1) provides a definition for the term "substantial doubt," 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The standard is effective for the Company's reporting year beginning January 1, 2017 and early adoption is permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In April 2015, the FASB issued accounting guidance requiring that debt issuance costs related to a recognized liability be presented on the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected. The standard is effective for reporting periods beginning after December 15, 2015. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In July 2015, the FASB issued accounting guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

In September 2015, the FASB issued accounting guidance to simplify the accounting for measurement period adjustments resulting from business combinations. Under the guidance, an acquirer will be required to recognize adjustments to provisional amounts identified during the measurement period in the reporting period in which the adjustments are determined. The guidance requires an entity to present separately on the face of the income statement or disclose in the notes to the financial statements the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment had been recognized as of the acquisition date. The standard is effective for reporting periods beginning after December 15, 2015. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. The Company is currently evaluating the impact, if any, that this new accounting pronouncement will have on its financial statements.

#### **Contractual obligations and off-balance sheet arrangements**

As of September 30, 2015 and December 31, 2014, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

#### **JOBS Act**

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (ii) December 31, 2019; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

#### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As a smaller reporting company, we are not required to provide the information required by this Item.

## Item 4. Controls and Procedures

### *Evaluation of Disclosure Controls and Procedures*

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of September 30, 2015. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

### *Changes in Internal Control over Financial Reporting*

On July 14, 2015, the Company completed the Merger by acquiring 100% of the capital stock of AdvanDx in the Merger. The Company has not yet completed an assessment of the design and/or operating effectiveness of AdvanDx's internal control over financial reporting. As of September 30, 2015, AdvanDx had total assets of \$2.6 million and AdvanDx generated revenues of \$0.8 million for the period subsequent to the Merger. There were no changes in the Company's internal control over financial reporting during the last quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## Part II — OTHER INFORMATION

### Item 1. Legal Proceedings

None.

### Item 1A. Risk Factors

In addition to the Risk Factors included in our Form 10-Q for the first quarter ended March 31, 2015, which are incorporated herein by reference, the Company adds the following risk factors:

***We have a history of losses, and we expect to incur losses for the next several years. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2014 and 2013 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.***

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the nine month periods ended September 30, 2015 and 2014 we had a net loss of \$12.6 million and \$4.3 million, respectively. From our inception through September 30, 2015, we had an accumulated deficit of \$109.4 million. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2014 and 2013 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. During the first nine months of 2015, the Company raised \$3.1 million in short-term notes and convertible debt (including \$1.0 million from Merck GHI, discussed below). In May 2015, the Company completed its IPO pursuant to which the Company offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an initial offering price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was \$12.1 million. In connection with the IPO, all of the Company's outstanding Series A Preferred Stock, 2014 convertible notes and 2015 convertible notes were converted into 7,374,852 shares of common stock. In July 2015, we received an additional investment of \$6.0 million as a result of an investment made in our common stock and a secured promissory note by Merck GHI. In addition, on July 14, 2015, we acquired AdvanDx pursuant to consummation of the Merger under the Merger Agreement.

We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- commercializing our Acuitas MDRO test products, Acuitas Lighthouse MDRO Management System and QuickFISH products, and potential future diagnostic and screening products and services;
- integration of the AdvanDx operations;
- developing, presenting and publishing additional clinical and economic utility data intended to increase clinician adoption of our current and future products and services;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize potential future products and services;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel; and
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a newly public company.

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy. We anticipate that we will need to raise additional capital to support our operations, including the operations of AdvanDx. While Merck GHI has the right to participate in future capital raising transactions, there is no assurance that it will invest further in the Company. We have no committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations could have an adverse effect on our business, financial condition and results of operations.

***We may fail to realize some or all of the anticipated benefits of the business combination of OpGen and AdvanDx, which may adversely affect the value of our common stock.***

The success of the integration of AdvanDx will depend, in part, on our ability to realize the anticipated benefits and cost savings from combining the respective business and operations of OpGen and AdvanDx. To realize these anticipated benefits and cost savings, we must successfully combine the acquired business with our legacy operations and integrate our respective operations, technologies and personnel, which is particularly challenging given the geographic and cultural differences between the personnel and facilities based in Maryland and Massachusetts, plus the European operations of AdvanDx, and the lack of experience we have in combining businesses. If we are not able to achieve these objectives within the anticipated time frame or at all, the anticipated benefits and cost savings of the acquisition may not be realized fully or at all or may take longer to realize than expected, and the value of our common stock may be adversely affected. In addition, the overall integration of the businesses is a complex, time-consuming and expensive process that, without proper planning and effective and timely implementation, could significantly disrupt our operations. Further, it is possible that the integration process could adversely affect our ability to maintain our research and development operations, result in the loss of key employees and other senior management, or to otherwise achieve the anticipated benefits of the acquisition.

Risks in integrating AdvanDx into our operations in order to realize the anticipated benefits of the acquisition include, among other factors:

- coordinating research and development activities to enhance the introduction of new diagnostic tests and technology acquired in the acquisition;
- failure to successfully integrate and harmonize financial reporting and information technology systems of the two companies;
- retaining each company's relationships with its partners;
- retaining and integrating key employees from OpGen and AdvanDx;
- managing effectively the diversion of management's attention from business matters to integration issues;
- combining research and development capabilities effectively and quickly;
- integrating partnership efforts so that new partners acquired can easily do business with us; and
- transitioning all facilities to a common information technology environment.

In addition, the actual integration may result in additional and unforeseen expenses, and the anticipated benefits of the integration plan may not be realized. Actual cost synergies, if achieved at all, may be lower than we expect and may take longer to achieve than anticipated. If we are not able to adequately address these challenges, we may be unable to successfully integrate the operations of the business acquired from AdvanDx into our own, or to realize the anticipated benefits of the integration. The anticipated benefits and synergies assume a successful integration and are based on projections, which are inherently uncertain, and other assumptions. Even if integration is successful, anticipated benefits and synergies may not be achieved. An inability to realize the full extent of, or any of, the anticipated benefits of the acquisition, as well as any delays encountered in the integration process, could have an adverse effect on our business and results of operations, which may affect the value of the shares of our common stock.

***We have incurred significant costs related to the Merger. If we are unable to offset the costs of the acquisition through realization of efficiencies, our financial condition, liquidity and results of operations will suffer.***

We have incurred, and expect to continue to incur, various non-recurring costs associated with combining the operations of OpGen and AdvanDx, including, but not limited to, legal, accounting and financial advisory fees. The substantial majority of non-recurring expenses have been composed of these costs and expenses related to the execution of the acquisition, facilities and systems consolidation costs and employment-related costs. We have also incurred fees and costs related to formulating and implementing integration plans. Additional unanticipated costs may be incurred in the integration of the businesses. Although we expect that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses, should allow us to offset incremental acquisition and acquisition-related costs over time, this net benefit may not be achieved in the near term, or at all.

***We expect to make significant additional investment in the future related to the acquisition of AdvanDx.***

We anticipate that we will need to make significant investments in the AdvanDx business in order to make it profitable. We will require additional capital to advance the AdvanDx line of products. Investing in the AdvanDx business could distract management attention and resources from the Company's current products and product development efforts. There can be no assurance that we can obtain sufficient resources or capital from operations or future financings to support the combined business operations. In the event the Company is unable to successfully raise additional capital, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances the Company would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing, or pursue other strategic alternatives which may include licensing and/or partnering arrangements or mergers and acquisitions.

***If we cannot enter into and maintain new clinical collaborations, our efforts to commercialize our existing products, and to further develop our products in development could be delayed.***

We have an existing collaboration with Hitachi High Technology related to the development of new products using our Whole Genome Mapping technology in human chromosome applications. We also seek collaborations with MDRO-related industry participants, which may include companies developing rapid diagnostic tests for MDROs, and partner with acute care hospitals in conducting clinical evaluations of our Acuitas MDRO test products. In addition, AdvanDx is likely to seek collaborative arrangement in the future as well. These collaborations are important to us. If any of our collaborators decides not to work with us in the future, or to curtail the scope of our collaboration, it could materially adversely affect our business.

***A number of the AdvanDx products are regulated by the FDA and non-U.S. regulatory authorities. If we or our suppliers fail to comply with ongoing FDA, or other foreign regulatory authority, requirements, or if we experience unanticipated problems with the products, these products could be subject to restrictions or withdrawal from the market.***

We do not have significant experience in complying with the rules and regulations of the FDA and foreign regulatory authorities. The AdvanDx products regulated as medical devices, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such products, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations for the manufacture, labeling, distribution and promotion of the AdvanDx products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions: (1) untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances or PMA approvals that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution.

***We are an early commercial stage company and our products may never achieve significant commercial market acceptance.***

Currently, we rely principally on the commercialization of our QuickFISH and Acuitas MDRO test products, and will rely on the launch and commercialization of our Acuitas Lighthouse MDRO Management System products and services, to generate future revenue growth. To date, the Acuitas MDRO test products have delivered only minimal revenue. We believe that our commercialization success is dependent upon our ability to significantly increase the number of hospitals, long-term care facilities and other inpatient healthcare settings that use our products. We have experienced very limited revenue and customer adoption for our Acuitas MDRO products to date. If demand for products does not increase as quickly as we have planned, we may be unable to increase our revenue levels as expected. We are currently not profitable. Even if we succeed in increasing adoption of our products by our target markets, maintaining and creating relationships with our existing and new customers and developing and commercializing additional molecular testing products, we may not be able to generate sufficient revenue to achieve or sustain profitability.

***Our products may never achieve significant commercial market acceptance.***

Our Acuitas MDRO test products and Acuitas Lighthouse MDRO Management System products and services may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our products will depend on several factors, including:

- our ability to convince the medical community of the clinical utility of our products and services and their potential advantages over existing tests;
- our ability to convince the medical community of the accuracy and speed of our products and services, as contrasted with the current methods available;
- the willingness of hospitals and physicians to use our products and services; and
- the recognition by inpatient health care facilities of the patient safety, improved outcome and cost-effectiveness benefits of using our products and the willingness to pay for them without reimbursement.

If any of these actions were to occur it could harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Some of the clearances obtained are subject to limitations on the intended uses for which the product may be marketed, which can reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

If we were to lose, or have restrictions imposed on, the FDA clearances received to date, our business, operations, financial condition and results of operations is likely to be significantly adversely affected.

## **Item 2. Unregistered Sales of Equity and Use of Proceeds**

### ***Unregistered Sales of Equity Securities***

On July 14, 2015, the Company completed the strategic acquisition of AdvanDx, through consummation of the Merger. Under the terms of the Merger Agreement, the Merger Consideration consisted of an aggregate 681,818 shares of the Company's common stock with a value of \$2.6 million (based on the closing sales price of our common stock of \$3.79 per share on July 13, 2015), which Merger Consideration was distributed in accordance with the liquidation preferences set forth in the AdvanDx Restated Certificate of Incorporation, as amended. The issuance of the Merger Consideration was effected as a private placement of securities deemed exempt from registration under Section 4(a)(2) of the Securities Act, and Rule 506 of Regulation D promulgated thereunder, regarding transactions by an issuer not involving a public offering. All stockholders of AdvanDx receiving Merger Consideration represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The stockholders received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration. The Company entered into a Registration Rights Agreement with the AdvanDx stockholders receiving Merger Consideration.

On July 14, 2015, the Company also entered into the Purchase Agreement, with Merck GHI, pursuant to which Merck GHI purchased 1,136,364 shares of common stock of the Company at \$4.40 per share for gross proceeds of \$5,000,000. Pursuant to the Purchase Agreement, the Company also issued to Merck GHI a Senior Secured Promissory Note, or the Note, and together with the shares of common stock purchased, the Securities, in the principal amount of \$1,000,000 with a two-year maturity date from the date of issuance. The Company's obligations under the Note are secured by a lien on all of the Company's assets pursuant to the terms of a Security Agreement, dated as of July 14, 2015, by and among the Company and AdvanDx, as debtors, and Merck GHI as the secured party. The sale of the Securities was effected as a private placement transaction deemed to be exempt from registration under Section 4(a)(2) of the Securities Act regarding transactions by an issuer not involving a public offering. Merck GHI, the sole purchaser of securities deemed to be exempt, represented to us that it was an accredited investor and was acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that it could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchaser received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration. The Company intends to use the proceeds from the sale of the Securities for working capital and other general corporate purposes, including funding AdvanDx's capital requirements in 2015 and 2016.

### ***Use of Proceeds***

On May 4, 2015 our registration statement on Form S-1 (File No. 333-202478) was declared effective by the SEC for our IPO. Maxim Group LLC acted as the sole book-running manager and National Securities Corporation acted as co-manager for the offering. On May 8, 2015, we completed our IPO pursuant to which we offered and sold 2,850,000 units, each consisting of one share of common stock and a detachable stock purchase warrant to purchase an additional share of common stock, at an IPO price of \$6.00 per unit. Of the total gross proceeds of \$17.1 million, approximately \$2.1 million was satisfied by exchanging outstanding demand notes. After considering the demand notes, underwriting discounts and commissions and offering expenses, the total net cash proceeds to the Company was \$12.1 million.

The principal purposes of our IPO were to obtain additional capital to support our operations, establish a public market for our common stock and to facilitate our future access to the public capital markets. We currently intend to use the net proceeds from this offering as follows:

- approximately \$5.0 million for sales and marketing activities, including expansion of our sales force to support the ongoing commercialization of our Acuitas MDRO Gene Test products and, when development is completed, our Acuitas Lighthouse MDRO Management System, and for working capital and general and administrative purposes;
- approximately \$4.0 million for research and development related to the continued support of our completion of the development of our Acuitas Lighthouse MDRO Management System and future products in our pipeline; and
- the remainder for general and administrative expenses (including compensation of our officers and directors and other personnel-related costs and costs of operating as a public company), and for working capital and other general corporate purposes.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on May 5, 2015. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries.

### **Item 3. Defaults Upon Senior Securities**

None.

### **Item 4. Mine Safety Disclosures**

Not applicable.

### **Item 5. Other Information**

None.

### **Item 6. Exhibits**

The exhibits listed in the Exhibit Index, which is incorporated herein by reference, are filed or furnished as part of this quarterly report on Form 10-Q.



**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 thereunto duly authorized.

**OPGEN, INC.**

By: /s/ Timothy C. Dec  
Timothy C. Dec  
Chief Financial Officer

Date: November 13, 2015

## EXHIBIT INDEX

| Exhibit<br>Number | Description  |
|-------------------|--|
| 2.1               | Agreement and Plan of Merger, dated as of July 14, 2015, among OpGen, Inc., Velox Acquisition Corp, AdvanDx, Inc., Stockholder Parties and Representatives (incorporated by reference to Exhibit 2.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)                  |
| 10.1              | Agreement and Plan of Merger, dated as of July 14, 2015, among OpGen, Inc., Velox Acquisition Corp, AdvanDx, Inc., Stockholder Parties and Representatives (incorporated by reference to Exhibit 2.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)                  |
| 10.2              | Common Stock and Note Purchase Agreement, dated as of July 14, 2015, between OpGen, Inc. and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)                                      |
| 10.3              | Senior Secured Promissory Note, dated as of July 14, 2015, between OpGen, Inc. and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)  |
| 10.4              | Registration Rights Agreement, dated as of July 14, 2015, among OpGen, Inc., Merck Global Health Innovation Fund, LLC, SLS Invest AB and LD Pensions (incorporated by reference to Exhibit 10.1 of Current Report on Form 8-K, File No. 001-37367, filed on July 16, 2015)                       |
| 10.5+             | Letter Agreement, dated July 12, 2015, between OpGen, Inc. and Fluidigm Corporation (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q, File No. 001-37367, filed on August 14, 2015)   |
| 10.6*             | Eighth Amendment to Lease Agreement, dated September 8, 2015, between ARE-708 Quince Orchard, LLC, as Landlord, and OpGen, Inc., as Tenant   |
| 31.1*             | Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)  |
| 31.2*             | Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)  |
| 32.1*             | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |
| 101*              | Interactive data files pursuant to Rule 405 of Regulation S-T; (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Cash Flows and (iv) the Notes to Unaudited Condensed Financial Statements.   |
| *                 | Filed herewith   |
| +                 | Confidential treatment has been granted through July 12, 2020 for certain portions of this agreement pursuant to an application for confidential treatment filed with the Securities and Exchange Commission on August 14, 2015. Such provisions have been filed separately with the Commission. |

## EIGHTH AMENDMENT TO LEASE AGREEMENT

**THIS EIGHTH AMENDMENT TO LEASE AGREEMENT** (“**this Eighth Amendment**”) is dated as of September 8, 2015 (“**Effective Date**”), by and between **ARE-708 QUINCE ORCHARD, LLC**, a Delaware limited liability company, having an address at 385 E. Colorado Blvd., Suite 299, Pasadena, California 91101 (“**Landlord**”), and **OPGEN, INC.**, a Delaware corporation, having an address at Suite 220, 708 Quince Orchard Road, Gaithersburg, Maryland 20878 (“**Tenant**”).

RECITALS

A. Landlord and Tenant have entered into that certain Lease Agreement (“**Original Lease**”) dated as of June 30, 2008, as amended by a First Amendment to Lease dated as of April 4, 2011 (“**First Amendment**”), a Second Amendment to Lease Agreement dated as of August 15, 2012 (“**Second Amendment**”), a Third Amendment to Lease Agreement dated as of December 30, 2013 (“**Third Amendment**”), a Fourth Amendment to Lease Agreement dated as of March 21, 2014 (“**Fourth Amendment**”), a Fifth Amendment to Lease Agreement dated as of March 20, 2015 (“**Fifth Amendment**”), a Sixth Amendment to Lease Agreement (And Amendment to Reimbursement Agreement) dated as of April 30, 2015 (“**Sixth Amendment**”), and a Seventh Amendment to Lease Agreement dated as of June 30, 2015 (“**Seventh Amendment**”; the Original Lease, the First Amendment, the Second Amendment, the Third Amendment, the Fourth Amendment, the Fifth Amendment, the Sixth Amendment, and the Seventh Amendment are hereinafter collectively referred to as the “**Lease**”), wherein Landlord leased to Tenant certain premises located on the first and second floors of the building located at 708 Quince Orchard Road, Gaithersburg, Maryland 20878, as more particularly described in the Lease.

B. Landlord and Tenant desire to amend the Lease, among other things, to provide an additional tenant improvement allowance to Tenant in an amount not to exceed \$65,000 (“**2015 TI Allowance**”) and to set forth the terms for Tenant’s repayment of the 2015 TI Allowance to Landlord.

AGREEMENT

Now, therefore, the parties hereto agree that the Lease is amended as follows:

1. **2015 TI Allowance.** Landlord shall provide the 2015 TI Allowance to Tenant, which amount Tenant shall use as set forth in this Eighth Amendment. Landlord’s obligations with respect to the 2015 TI Allowance shall cease upon disbursement in full of the 2015 TI Allowance to or on behalf of Tenant. The 2015 TI Allowance shall be used to reimburse Tenant only for modifications of or improvements to the Premises of a fixed and permanent nature desired by Tenant previously approved by Landlord (“**Tenant Improvements**”) but shall not be used to purchase any furniture, personal property, or other non-Building Systems materials or equipment. Tenant shall have no right to the use or benefit (including any reduction to Base Rent) of any portion of the 2015 TI Allowance not required for the Tenant Improvements. As of the Effective Date, Tenant is in the process of constructing the Tenant Improvements in accordance with the terms and conditions of the Lease. Upon submission by Tenant to Landlord of a single request for payment (“**Payment Request**”) containing written evidence (including invoices and receipts) of the expenses incurred by Tenant with respect to the Tenant Improvements, Landlord shall promptly reimburse Tenant for such expenses from the 2015 TI Allowance, but only to the extent of the funds are available therefrom. Tenant shall submit such Payment Request not later than the first anniversary of the Effective Date. Landlord shall have no obligation to so reimburse Tenant for the expenses incurred by Tenant in connection with the Tenant Improvements if Tenant submits such Payment Request after the first anniversary of the Effective Date.



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2. **Repayment of 2015 TI Allowance.** Base Rent shall be increased as of the date on which Landlord reimburses Tenant pursuant to the Payment Request (such increase to be calculated based on the amount of the 2015 TI Allowance used by Tenant and as set forth in the Payment Request, such amount to be amortized over the remaining portion of the Second Extension Term based on an interest rate of 9% per annum; the resulting amount so amortized shall be added to the monthly installments of Base Rent).

3. **Amended Definition of “Termination Fee.”** As of the Effective Date, the definition of “Termination Fee” set forth in the second sentence of Section 43(c) is hereby deleted and replaced with the following sentence:

For purposes of this Section, “**Termination Fee**” means an amount equal to the unamortized amounts of (i) 2015 Landlord’s Work (as defined in the Fifth Amendment) and 2015 Expansion Premises Work (as defined in the Seventh Amendment), (ii) the leasing commissions paid by Landlord in connection with the Fifth Amendment and Seventh Amendment, (iii) the Rental Abatement (as defined in the Fifth Amendment), and (iv) the 2015 TI Allowance (as defined in the Eighth Amendment).

4. **Miscellaneous.**

a. Terms used in this Eighth Amendment and not otherwise defined shall have the meanings ascribed to them in the Lease.

b. This Eighth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Eighth Amendment may be amended only by an agreement in writing, signed by the parties hereto.

c. This Eighth Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, members, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

d. This Eighth Amendment may be executed in any number of counterparts, each of which shall be deemed an original, but all of which when taken together shall constitute one and the same instrument. The signature page of any counterpart may be detached therefrom without impairing the legal effect of the signature(s) thereon provided such signature page is attached to any other counterpart identical thereto except having additional signature pages executed by other parties to this Eighth Amendment attached thereto.



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e. Except as amended and/or modified by this Eighth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Eighth Amendment. In the event of any conflict between the provisions of this Eighth Amendment and the provisions of the Lease, the provisions of this Eighth Amendment shall prevail. Regardless of whether specifically amended by this Eighth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Eighth Amendment.

**[Signatures on Next Page]**



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IN WITNESS WHEREOF, the parties hereto have executed this Eighth Amendment under seal as of the day and year first above written.

**TENANT:**

**OPGEN, INC.,**  
a Delaware corporation

By: /s/ Timothy C. Dec (SEAL)  
Name: Timothy C. Dec  
Title: Chief Financial Officer

**LANDLORD:**

**ARE-708 QUINCE ORCHARD, LLC,**  
a Delaware limited liability company

By: ARE-GP 708 Quince Orchard QRS CORP.,  
a Maryland corporation,  
managing member

By: /s/ Jennifer Banks (SEAL)  
Name: Jennifer Banks  
Title: EVP, General Counsel



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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO RULE 13A-14(A)/15D-14(A)**

I, Evan Jones, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OpGen, 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 we 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 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: November 13, 2015

/s/ Evan Jones

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Evan Jones

Chief Executive Officer (principal executive officer)

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**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO RULE 13A-14(A)/15D-14(A)**

I, Timothy C. Dec, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OpGen, 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 we 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 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: November 13, 2015

/s/ Timothy C. Dec

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Timothy C. Dec

Chief Financial Officer (principal financial officer  
and principal accounting officer)

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**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 quarterly report on Form 10-Q of OpGen, Inc. (the "Company") for the quarterly period ended September 30, 2015 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

This certification is provided solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Date: November 13, 2015

By: /s/ Evan Jones  
Evan Jones  
Chief Executive Officer (principal executive officer)

Date: November 13, 2015

By: /s/ Timothy C. Dec  
Timothy C. Dec  
Chief Financial Officer (principal financial officer and principal accounting officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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