

Akers Biosciences, Inc.
Form NT 10-K
April 03, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 12b-25

NOTIFICATION OF LATE FILING

SEC FILE NUMBER: 333-200529

CUSIP NUMBER: 746040104

[X] Form 10-K [] Form 20-F [] Form 11-K [] Form 10-Q [] Form N-SAR
(Check One):
[] Form N-CSR

For Period Ended: **December 31, 2017**

[] Transition Report on Form 10-K
[] Transition Report on Form 20-F
[] Transition Report on Form 11-K
[] Transition Report on Form 10-Q
[] Transition Report on Form N-SAR

For the Transition Period Ended: _____

Read Instruction (on back page) Before Preparing Form. Please Print or Type.

Nothing in this form shall be construed to imply that the Commission has verified any information contained herein.

If the notification relates to a portion of the filing checked above, identify the item(s) to which the notification relates:

PART I — REGISTRANT INFORMATION

AKERS BIOSCIENCES, INC.

Full name of registrant:

N/A

Former name if applicable:

201 Grove Road

Address of principal executive office (Street and number):

Thorofare, NJ 08086

City, state and zip code

PART II — RULES 12b-25(b) AND (c)

If the subject report could not be filed without unreasonable effort or expense and the registrant seeks relief pursuant to Rule 12b-25(b), the following should be completed. (Check box if appropriate.)

- (a) The reasons described in reasonable detail in Part III of this form could not be eliminated without unreasonable effort or expense;

[X] (b) The subject annual report, semi-annual report, transition report on Form 10-K, Form 20-F, 11-K or Form N-SAR, or portion thereof, will be filed on or before the fifteenth calendar day following the prescribed due date; or the subject quarterly report or transition report on Form 10-Q, or portion thereof will be filed on or before the fifth calendar day following the prescribed due date; and

- (c) The accountant's statement or other exhibit required by Rule 12b-25(c) has been attached if applicable.

PART III — NARRATIVE

State below in reasonable detail the reasons why Forms 10-K, 20-F, 11-K, 10-Q, N-SAR, N-CSR, or the transition report or portion thereof, could not be filed within the prescribed time period.

The Company was unable, without unreasonable effort or expense, to file its Annual Report on Form 10-K for the period ended December 31, 2017 ("Form 10-K") by April 2, 2018. The Company requires additional time to gather information and finalize its financial statements. The Company expects to file the Form 10-K within the additional time allowed by this report.

PART IV — OTHER INFORMATION

(1) Name and telephone number of person to contact in regard to this notification

John J. Gormally (856) 848-2116
(Name) (Area Code) (Telephone Number)

(2)

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Have all other periodic reports required under Section 13 or 15(d) of the Securities Exchange Act of 1934 or Section 30 of the Investment Company Act of 1940 during the preceding 12 months or for such shorter period that the registrant was required to file such report(s) been filed? If the answer is no, identify report(s).

☒ Yes ☐ No

(3) Is it anticipated that any significant change in results of operations from the corresponding period for the last fiscal year will be reflected by the earnings statements to be included in the subject report or portion thereof?

☒ Yes ☐ No

If so, attach an explanation of the anticipated change, both narratively and quantitatively, and, if appropriate, state the reasons why a reasonable estimate of the results cannot be made.

The Company expects to report that the Company's investments in marketable securities as of December 31, 2017 are \$5,011,607 up from \$50,001 during the same period in 2016.

The Company expects to report that Company's product revenue increased by 31% to \$3,879,527 during the year ended December 31, 2017, compared to \$2,957,162 during the same period in 2016. This increase is due to the fact that the Company's PIFA Heparin/PF4 Rapid Assay products generated the majority of the product revenue but the growth was driven primarily by sales of BreathScan Alcohol Breathalyzers, BreathScan OxiChek™ and the Company's re-introduced Tri-Cholesterol products. License and service fees increased to \$50,000, compared to \$3,750 during the same period in, the result a fee from a potential customer for the Company's BreathScan OxiChek™ products in exchange for the use of equipment, access to product documentation and data, technical support and to restrict the Company from actively pursuing another commercial partner in a specific market segment

The Company expects to report that Company's revenue from PIFA Heparin/PF4 Rapid Assay products decreased 13% to \$2,232,684 from \$2,577,148 during the same period in 2016.

The Company expects to report that the Company did not recognize any revenue from the Company's PIFA Heparin/PF4 Rapid Assay products from the Company's distribution partner in the People's Republic of China, compared to \$505,380 during the same period in 2016. Revenue from China continues to be highly unpredictable. NovoTek Pharmaceuticals ("NovoTek"), our distribution partner for the PIFA Heparin/PF4 Rapid Assay products, continues to pursue approvals for reimbursement rates from the various Provinces and although they anticipate receipt of these approvals, their timing is unknown. Over the past several years, NovoTek has created significant product demand by identifying and working with the key opinion leaders and seeding the marketplace with sample products. As a result, they anticipate strong demand for the PIFA Heparin/PF4 Rapid Assay product once reimbursement rates are approved.

The Company expects to report that the Company's MPC product sales increased by 237% to \$950,946 during the year ended December 31, 2017 from \$282,516 during the same period in 2016. This increase is due to a distributor's initial stocking order of \$267,750 for the Company's BreathScan Alcohol Breathalyzer products in Australia and New Zealand and revenue from the Company's new BreathScan Lync™ and BreathScan OxiChek™ products contributed to the increase for the year ended December 31, 2017.

The Company expects to report that due to its re-introduction of its Tri-Cholesterol test it generated \$133,848 this year. The Company expects to report that direct costs of sales for the year ended December 31, 2017, were \$809,059 compared to \$448,240 during the same period in 2016, and that other cost of sales for the year ended December 31, 2017, were \$610,904 compared to \$634,848 during the same period in 2016. The initial commercial production of the Company's Tri-Cholesterol product contributed to the increase in direct costs. One-time costs associated with the transition from Research and Development to Manufacturing as the production plans were implemented and adjusted included engineering, raw material waste as processes were fine-tuned to meet commercial production levels, training

of the production staff and increased quality review and testing. The inclusion of several of the Research and Development department's professional staff as part of the initial production team significantly increased direct labor costs.

The Company expects to report that other operating revenue increased by 476% to \$562,049 for the year ended December 31, 2017, compared to \$97,498 during the same period in 2016. The significant increase resulted from an initial order, for manufacturing components from NovoTek totaling \$500,000.

The Company expects to report that License and service fee revenue increased to \$50,000 during the year ended December 31, 2017, compared to \$3,750 during the same period in 2016. The Company received a non-refundable \$50,000 fee from a potential customer for the Company's BreathScan OxiChek™ products in exchange for the use of equipment, access to product documentation and data, technical support and to restrict the Company from actively pursuing another commercial partner in a specific market segment.

The Company expects to report that personnel costs rose 32% to \$1,173,964 for the year ended December 31, 2017, compared to \$886,294 during the same period in 2016. The increase is the result of changes to compensation for the Chief Executive Officer and Vice President of Finance, including base salaries, bonus and equity, and the establishment of a Financial Controller position to support daily operations and assist in the implementation of revised internal and disclosure controls. Professional service costs increased by 53% for the year ended December 31, 2017 as compared to the same period of 2016. A significant increase in accounting and audit, personnel recruitment, engineering, legal fees, and general consulting services accounted for the change. The Company also expects to report that it renegotiated or eliminated several consulting arrangements during the years ended December 31 2017 and 2016. The result is a reduction of 42% in professional service fees. Additionally, the Company expects to report that personnel costs for research and development increased 28% during the year ended December 31, 2017 as compared to the same period of 2016. The increase is the result of changes to the compensation for the Chief Scientific Director as he assumed his new expanded responsibilities for the Company.

The Company's expects to report that its other general and administrative expenses increased by 40% for the year ended December 31, 2017 as compared to the same period of 2016.

The Company expects to report that clinical trial costs decreased 98% during the year ended December 31, 2017 as compared to the same period of 2016. The Company performed two clinical trials during the year ended December 31, 2016, one to test the effectiveness of the PIFA Chlamydia assay and one for Breath DKA. The trials collected data to support submissions to the U.S. Food and Drug Administration for 510(k) approvals and to support the clinical effectiveness of the products.

The Company's expects to report that its other income decreased 51% to \$12,412 from \$25,097 during the same period in 2016, and other expenses totaled \$764,932 for the year ended December 31, 2017, compared to no other expenses during the same period in 2016.

The Company expects to report that realized gains, interest and dividend income declined to \$10,753 from \$21,699 during the same period in 2016. The Company's available capital for investment activities was limited during the year ended December 31, 2017 resulting in the decline in investment income. The Company modified the exercise price for 724,200 warrants issued March 30, 2017 from \$1.96 to \$1.00 per common share and issued an additional 724,200 warrants to the original holders at an exercise price of \$1.26 per common share to raise additional capital. The Company incurred extraordinary expenses of \$764,932, the fair value of the modification, as a result of the transaction in accordance with FASB ASC 718-20-35.

The Company expects to report that the Company's net cash consumed by operating activities in the year ended December 31, 2017 totaled \$5,080,412, which was a 22% increase as compared to \$4,173,148 for the year ended December 31, 2016.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This notification of Late Filing on Form 12b-25 contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this notification of Late Filing on Form 12b-25, including statements regarding the Company's strategy, future operations, future product research or development, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "goals," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forwardlooking statements as a result of various important factors, including: the occurrence of any event change or other circumstances that could give rise to

the termination of the License Agreement with Roche, the uncertainties inherent in receiving future payments pursuant to the License Agreement, the uncertainties inherent in the initiation and conduct of clinical trials, the Company's ability to successfully develop the Company's product candidates and complete the Company's planned clinical programs, the Company's ability to obtain marketing approvals for the Company's product candidates, expectations regarding the Company's ongoing clinical trials, availability and timing of data from clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical studies will be indicative of the results of future studies, the adequacy of any clinical models, expectations regarding regulatory approvals, the Company's ability to obtain, maintain and protect the Company's intellectual property for the Company's technology and products, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, other matters that could affect the financial performance of the Company, other matters that could affect the availability or commercial potential of the Company's product candidates and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

AKERS BIOSCIENCES, INC.

(Name of Registrant as Specified in Charter)

has caused this notification to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 3, 2018 By/s/ *John J. Gormally*
John J. Gormally
Chief Executive Officer

INSTRUCTION. The form may be signed by an executive officer of the registrant or by any other duly authorized representative. The name and title of the person signing the form shall be typed or printed beneath the signature. If the statement is signed on behalf of the registrant by an authorized representative (other than an executive officer), evidence of the representative's authority to sign on behalf of the registrant shall be filed with the form.

ATTENTION

Intentional misstatements or omissions of fact constitute Federal criminal violations. (See 18 U.S.C. 1001).

