November 8, 2023

Zacks Small-Cap Research (NOTE)

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Bluejay Diagnostics, Inc. (BJDX: NASDAQ)

BJDX: Toray License Renegotiation

Research Note

Bluejay Diagnostics, Inc. (NASDAQ: BJDX) has presented several pieces of material news in the last months adding a new CFO to its ranks, raising capital and renegotiating its license agreement with Toray Industries, Inc. Frances Scally was added as CFO of the company on September 26th following the former CFOs departure. The company raised gross proceeds of $1.59 million in an at-the-market transaction which closed at the end of August. Bluejay also renegotiated its license agreement with Toray, reducing the previous royalty rate owed to the license holder by half.

New Chief Financial Officer

In a Form 8-K filing, Bluejay announced that it had appointed Frances Scally as interim CFO and designated her as the company's principal financial officer and principal accounting officer. Ms. Scally will be assisted by Scott Levy to support the company's financial functions. Both Ms. Scally and Mr. Levy are employees of DLA, LLC which is an accounting advisory practice. Ms. Scally has previously served in financial roles for SeqLL Inc., Aceto Holdings, L.P., Veeco Instruments and Ernst & Young.

Ken Fisher, Bluejay's previous CFO had previously announced that he would depart the company to pursue other interests.

Capital Raise

In an August 25th press release, Bluejay announced an at-the-market offering to raise gross proceeds of $1.59 million. The company issued 216,000 shares priced at $7.365 along with 216,000 warrants with an exercise price of $7.24. The warrants have a five-year duration. Funds from the raise will be used to advance the Symphony diagnostic through the FDA's regulatory process, research and development activities and general working capital needs. Bluejay is now working towards another capital raise which will enable the start of its pivotal trial which will pursue the 510(k) regulatory pathway.

Renegotiation with Toray Industries

An October 26th Form 8-K filing announced that Bluejay Diagnostics has amended its license agreement with Toray Industries. Under the previous agreement, Toray had agreed to provide the Symphony device, cartridge and license to commercialize worldwide, excluding Japan, in return for a 15% royalty, licensing fees and minimum payments. However, Toray had moved away from manufacturing the Symphony components for commercialization and a new arrangement was necessary. Furthermore, under the old agreement, Bluejay was required to make commercially reasonable efforts to obtain market approval in the US and EU by October 2023, which could not be met.

Under the new agreement, Bluejay will continue to license the rights to the Symphony system components and will be able to sublicense certain intellectual property to Sanyoseiko, who will manufacture Symphony components during commercialization. The new agreement reduced the royalty rate from 15% to 7.5% for a term of 10 years. If regulatory approval is denied due to quality problems attributable to Toray, the royalty rate may be reduced to 4%. New

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products are recognized under the renegotiated agreement and arrangements for the use of Toray intellectual property will be determined in the future for these arrangements. Bluejay is required to start commercial sales within five years of the effective date of the amended license agreement, which will be October 2028. If a delay beyond this period is due to factors outside Bluejay's control, a two-year extension may be granted after which the license agreement may become non-exclusive.

Toray will continue to manufacture certain intermediary cartridge components for use by Sanyoseiko which will be used for obtaining regulatory approval and not for commercial sale. The supply agreement has a term that will end the earlier of October 23rd, 2025 or upon regulatory approval of the product.

The new agreement clarifies the ownership of newly developed intellectual property which was not discussed in the earlier agreements. Intellectual property solely developed by either Toray or Bluejay will be solely owned by Toray or Bluejay. Intellectual property developed with a contribution from both parties will be owned by both, with ownership of the property to be proportional with each party's contribution.

The change in the arrangement is not a surprise as it was clear that Toray would not be manufacturing the device and related components for commercialization, which was required under the old arrangement. The model developed for our initiation made a conservative assumption that Bluejay would pay both the 15% royalty and product cost to Sanyoseiko. This new arrangement makes it clear that Toray will not provide commercial product to Bluejay and in return will receive a lower royalty.

Summary

Bluejay is on the cusp of launching its pivotal trial for the Symphony IL-6 test in the indication for risk stratification of hospitalized sepsis patients. After consultation with the FDA, the 510(k) pathway has been confirmed and the management team is identifying large, well-known medical and academic institutions for its study. A new CFO and small capital raise allow Bluejay to conduct the preparation work necessary to access further capital in order to fund the upcoming trial which we estimate will cost $15 million. Now that the uncertainty regarding the royalty and product supply arrangements have been clarified, we anticipate news in the near term regarding trial disposition.

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