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NightHawk Biosciences, Inc. (NHWK: NASDAQ)

NHWK: Transformational Changes

Research Note

NightHawk Biosciences, Inc. (NYSE: NHWK) reported 3Q:23 results on November 20th, 2023 as published in a press release and in the filing of its Form 10-Q. Since our previous update in October, the company has announced transformational changes electing to divest the Elusys unit, step away from biodefense and de-emphasize research activities. In 2024 and beyond, the company will focus on its biomanufacturing contract development and manufacturing organization (CDMO). Prompted by the narrowing in focus, the company will change its name to Scorpius Holdings in the next few weeks, sporting the new ticker symbol SCPX. Following the report of the third quarter, NightHawk highlighted several CDMO revenue opportunities including newly booked contracts valued at over $20 million, completion of a manufacturing run for a biopharmaceutical company and demonstration runs for a research university that bode well for the business.

Third Quarter Results

For 3Q:23, NightHawk generated revenues of $0.7 million and posted a net loss of ($13.1) million, or ($0.50) per share. As of September 30, 2023, NightHawk holds a cash balance of $6.2 million. These results do not include $6.7 million of Anthim-related product sales included in discontinued operations related to a contract with the US Department of Health and Human Services that was completed on September 13th, 2023.

For the quarter ending September 30, 2023 versus the same prior year period:

- Continuing revenues were $0.7 million, down from the prior year's $6.0 million which were derived from process development ($0.6 million) and service revenue ($0.1 million). Prior year results included revenues related to product sales from last year's Anthim delivery and $60,000 of contract revenue;
- Product cost of sales was $0.5 million vs. nil which related to Scorpius' labor, overhead and material costs. This equates to a gross margin of 25%;
- Research & development expenses totaled $5.2 million, down 25% from $6.9 million, driven primarily by lower spending on the oncology programs and the absence of spending on Anthim development as these expenses are categorized as discontinued;
- General & administrative expenses were $6.1 million, a 19% lift from $5.1 million, on greater marketing, personnel, depreciation & amortization and rent expense. This was offset by a decline in insurance expense;
- Total other non-operating items were ($3.1) million related to discontinuing operations;
- Net loss was ($13.1) million, or ($0.50) per share, compared to ($13.0) million or ($0.51) per share.

At the end of the third quarter, NightHawk held cash, equivalents and short-term investments totaling $6.2 million, compared to $44.3 million at the end of 2022. Cash used in operations and capital expenditures for 3Q:23 was ($9.2) million, compared to a ($12.3) million contribution in 3Q:22. For the first nine months of 2023, cash burn was ($32.1) million. Following the restructuring announcement, we anticipate future cash burn will be substantially reduced.

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New Focus on Contract Development and Manufacturing Organization (CDMO)

NightHawk has gone through a metamorphosis over the last few years evolving from an oncology research and development company to a broad biosciences company that added national defense assets and biomanufacturing to its lineage in cancer investigation. With rising interest rates and access to capital near impossible for small cap life sciences companies, NightHawk elected to narrow its operations to consistent revenue generating businesses with high near-term growth rates. This change has led to management's decision to divest all businesses that are non-core to the company's future in biomanufacturing. Elusys will be sold, Skunkworx, Pelican and Heat Biologics already have been or will be wound down leaving Scorpius BioManufacturing as the only operating unit.

The change will eliminate $40 million in commitments and reduce operating expenditures by over $13 million per year. Following 2023's first full year of CDMO operations, Scorpius has generated substantial bookings that we expect to see come across the topline in 2024. The company booked $20 million in revenue in 2023 and has also completed a manufacturing run for a "premier US-based biopharmaceutical company." Additional press releases highlighted further work for the unit with completion of a demonstration run for a NIH and DTRA funded research university and begins work to develop a substance abuse biologic.

New Senior Leadership Added

In conjunction with its announcement of a corporate name and ticker change, NightHawk also announced the appointment of several new senior individuals to support the growth of the CDMO. Two vice presidents, one senior director and a site head of quality were appointed providing a broad range of experience to Scorpius.

Brian O'Mara - VP of Process Sciences. Mr. O'Mara joined Scorpius in June 2022 as the Senior Director, Manufacturing Science & Technology. He has more than 20 years of industrial biotechnology experience in downstream process development of early- and late-stage protein therapeutics from mammalian and microbial expression systems. He also has extensive experience in the development and scale-up of protein conjugates, including antibody-drug conjugates (ADCs), bi-specifics, and PEGylated molecules, as well as experience in technology transfer, CDMO management, process characterization, preparation and oversight of PPQ campaigns, and associated CMC regulatory filings. Brian earned a BS in Biology from Binghamton University and an MS in Chemistry from Lehigh University.

Steve Lavezoli - VP of Commercial Operations. Mr. Lavezoli joined Scorpius in December 2022 as the Regional VP of Business Development for the central region. He now oversees Scorpius' business development, proposals, and marketing strategy. He brings extensive experience in various roles throughout business development and marketing. He spent 12 years in the industrial gasses industry with Linde Gas, as well as W.L. Gore in their Startup Biopharmaceutical division working on a Commercial Business/Market Development role for Bulk Drug Substance Single-Use items. He also spent 3 years with Catalent Biologics, focused on Drug Substance Business Development in the US for early-stage clinical programs with clients to bring life-changing therapies to the market. Steve holds a BS in Chemical Engineering from Pennsylvania State University and an MBA in Marketing from Robert Morris University.

Juan Lagos - Senior Director of Cell-Based Technologies. Mr. Lagos brings more than 20 years of experience in cell culture and upstream process development from lab bench to cGMP manufacturing and leads Scorpius' cell-based technologies team, which is responsible for analytical and cell therapy processes. Before joining Scorpius, he was the Associate Director MS&T / LVV Suspension Process Development at Rocket Pharmaceuticals. His industry experience includes director-level and senior engineering roles at Allakos and Bristol Myers Squibb, as well as experience at biopharma service providers like WuXi Apptec and Patheon. He holds a dual B.S. in Computer Science and Chemical Engineering from Rutgers University, where he continues to pursue a Ph.D. in Biochemical Engineering.

Ania Szymanska - Site Head of Quality. Ms. Szymanska brings over 19 years of leadership and management experience in Quality Control, Quality Assurance, and Compliance at pharmaceutical and biotech companies. She joined Scorpius from Marker Therapeutics, Inc. where she was Vice President of Quality and built the Quality Management Systems. She played a critical role in the design, construction, and qualification of their state-of-the-art cell therapy GMP manufacturing facility and Quality Control laboratories. Prior to Marker, she served as Director of Quality Control for Bellicum Pharmaceuticals, Inc. where she developed its Quality Control department and was responsible for aseptic facility qualification. She also served as Quality Validation Specialists of Opexa Therapeutics, Inc. and in roles of increasing responsibility at Woodfield Pharmaceutical, LLC (formerly Pernix Manufacturing, LLC), most recently as Director of Microbiology. Ms. Szymanska earned an M.S. in Microbiology from the University of Warsaw.

Summary

NightHawk has narrowed its focus from a fully-integrated biopharmaceutical company to its San Antonio CDMO. The market environment has not been friendly to businesses that lack revenues and earnings, reducing the attractiveness of research and development-based assets. Fortunately, NightHawk, soon to be Scorpius Holdings, has built an attractive CDMO that is generating revenues and could tip into the realm of positive free cash flow in the next year or so. There remain a lot of moving parts and untangling, especially the capital structure following all of the wind-downs and divestitures, so we will we watching closely for the upcoming annual filing to refine our financial statements and estimates. Based on our read, there is more demand that supply in the CDMO space, and now that the San Antonio facility if fully operational, we anticipate that the unit will reach normal operating capacity in the near term.

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