Zacks Small-Cap Research

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AnPac Bio-Medical Science Co., Ltd.

(ANPC - NASDAQ)

2020 Financial & Operational Results

Target price is based on a 20x multiple of 2027 EPS. The result is discounted to present at a 25% rate. Revenues represent contributions from physical checkup packages and cancer screening tests in China and the United States.

Current Price (5/7/2021)	$4.69
Valuation	**$8.00**

OUTLOOK

AnPac Bio is developing advanced cancer screening with its CDA technology that is able to detect the likelihood of 26 different cancers. The screening tool can serve a valuable role in early detection and prevention of this common disease.

Historical revenues are solely generated in China from cancer screening and detection and physical checkup packages. Future growth will come from access to the Chinese hospital market and launch of testing services in the United States.

AnPac is focused on obtaining the license and authorization to provide services more broadly in China that come from approval of Class III registration. The company is also working to launch testing services in the US having obtained a CLIA & CAP approved lab in California. Efforts to conduct clinical trials to validate the diagnostic platform and to seek FDA approval of its CDA testing platform is also underway. ANPC will initially sell the diagnostic as an LDT and later seek FDA approval for its tests, allowing for broader use.

SUMMARY DATA

52-Week High	**12.09**
52-Week Low	**3.15**
One-Year Return (%)	**-39.6**
Beta	**1.9**
Average Daily Volume (sh)	**937,082**
Shares Outstanding (mil)	**12.7**
Market Capitalization ($mil)	**59.5**
Short Interest Ratio (days)	**0.2**
Institutional Ownership (%)	**1.8**
Insider Ownership (%)	**43.2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Instruments**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$0.0 A	$0.0 A	$0.0 A	$1.6 A	$1.6 A
2020	$0.0 A	$0.6 A	$0.0 A	$2.6 A	$3.1 A
2021					$6.5 E
2022					$11.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$0.00 A	$0.00 A	$0.00 A	-$1.62 A	-$1.62 A
2020	$0.00 A	-$0.72 A	$0.00 A	-$0.39 A	-$1.10 A
2021					-$0.44 E
2022					-$0.23 E

WHAT'S NEW

Fiscal Year 2020 Results

On April 30, 2021, AnPac Bio-Medical Science Co., Ltd. (NASDAQ: ANPC) issued a press release summarizing its financial and operational results for the year ended December 31, 2020. A conference call and webcast were held the same morning along with the filing of the company's Form 20-F later that day. AnPac posted strong growth for 2020, despite impacts from the pandemic. Growth was near 90% in local currency for the year and approximately 100% in dollar terms. The first quarter of 2021 has started off very strong, albeit on a prior year period that was negatively impacted by the pandemic. Testing volume increased 130% to 5,439 tests over the first three months of the year.

Highlights for FY:20 include:

- Listing on the NASDAQ in January 2020;
- New product launches, AnPac Defense Medical Examination (ADME) and AnPac Pan Cancer Screening (APCS);
- Continued validation of CDA efficacy through study follow-up;
- Increased data in the CDA cancer risk database;
- CAP certification for AnPac's San Jose, California laboratory;
- CLIA certification for AnPac's Philadelphia, Pennsylvania laboratory.

In fiscal year 2020, AnPac generated revenues of $3.1 million, an increase of 89.1%[1] over fiscal 2019 revenues. This was primarily due to increases in cancer screening and detection test revenue. Loss per share was ($1.10), compared with our estimate of ($0.99).

For the fiscal year ending December 31, 2020, compared to the fiscal year ended December 31, 2019:[2]

- Revenues were $3.1 million, up 89% from $1.6 million, driven by increased cancer screening and detection test revenue. Revenue per test of $68.40 rose 125% and was the primary driver of the sales increase on test volume of 41,354 which fell from 52,428 in the prior year period due to effects from the pandemic.
- Cost of revenues increased 34.5% to $1.2 million from $0.9 million on a higher number of comprehensive multi-cancer detection tests performed, which resulted in increased costs related to testing materials, out-sourced biomarker-based tests, blood sample taking and medical consumables;
- Gross margin was 62.8% versus 44.2%;
- Selling and marketing expenses were $3.0 million, increasing 54% from $2.0 million with increased market-ing efforts partially offset by lower share-based compensation;
- Research and development expenses increased 25.6% to $1.8 million from $1.4 million with increased R&D activity, higher R&D related depreciation and greater staff costs;
- G&A expenses were $11.5 million, increasing 12.7% from $10.2 million, primarily due to increased ex-change listing-related fees and increased employee compensation;
- Net loss was ($12.3) million, decreasing 15% from ($14.5) million, or ($1.10) per share versus ($1.62) per share.

As of December 31, 2020, cash and equivalents totaled $462,000. Cash burn for the year was ($9.4) million nearly offset by $9.3 million in cash from financing. Following the reporting period, AnPac has raised funds from both equi-ty and debt in 2021 and based on disclosures in Form 20-F we estimate cash from financing year to date of $3.6 million.

[1] The percentage increase is calculated in Chinese renminbi.
[2] Note that our percentage change is based on reported income statement values in US Dollars which differs from AnPac's calculation using Renminbi.

Class III Registration Advancing in Lung Cancer

AnPac applied for a Class III medical device registration certificate in December 2018 to use the CDA device for multi-cancer diagnosis. In an update on February 8, 2021, AnPac disclosed that registration testing for its Class III medical device certification was approved to begin by the NMPA, marking a milestone on the road to further commercialization in China. The application specifies a lung cancer auxiliary diagnosis medical device. Pursuing a single site for cancer screening rather than a pan cancer approach was a strategic decision that is expected to save time given its improved tractability. CDA requires additional testing to determine the specific cancer; therefore, an auxiliary test, available via third party, is expected to accompany CDA to obtain approval in lung cancer. Further applications in pan-cancer indications are expected and the company will pursue the routes that most expediently clear the device to generate testing revenues.

Successfully achieving the objectives of the test will allow AnPac to place CDA diagnostic equipment in hospitals, the primary setting for annual physical checkups administered to 100 million Chinese citizens every year. We estimated that AnPac might obtain this authorization by late 2021, but progress will depend on clinical bandwidth, which may be limited by the pandemic and associated containment measures and we see a delay from this target. The process for NMPA approval typically takes three years and was begun in December 2018 when AnPac applied for medical device registration. Since then, the device was classified by the NMPA as a highly regulated Class III device. AnPac has optimized and tested the device internally and employed third party testing and validation. AnPac has obtained the necessary certification for the device testing laboratory where the recently NMPA-approved testing will begin. Pending successful product registration testing, the next step will be a clinical trial. AnPac anticipates that the clinical trial will be conducted in at least two qualified medical institutions, targeting enrollment of 300 subjects for each clinical site. The trial will differ from conventional clinical trials as the results will primarily only require sample collection and confirmation of the cancer using a gold-standard technique. There is no treatment involved which is favorable in terms of time and cost. Timelines will coalesce once the trial is underway, and uncertainties regarding clinical availability and throughput will be clarified. Pending favorable results from the trial, AnPac leadership expects CDA to receive the benefit of an accelerated pathway under the NMPA, but cautions that COVID-19 related therapies and products have taken priority.

In the most recent conference call, management provided further detail regarding the steps required for obtaining Class III Registration, summarized below.

- Deliver the CDA machine to the lab for testing
- Conduct and pass required testing
- Develop clinical study design
- Begin clinical portion of testing with three machines delivered to three hospitals
    - Three to six month timeline to conduct necessary studies
- Collect, analyze and submit data package to the Chinese regulatory authorities for review
- Address additional requests for data
- Receive approval when all requirements satisfied and questions answered

The process for obtaining approval is uncertain and depends heavily on what the regulatory authorities want to see from the submission. The timeline could extend from eight months to a year and we expect further updates as the steps in the process are clarified.

Detecting Pre-cancer Diseases

For all of the individuals who have taken the commercial CDA tests, AnPac follows up with them at regular intervals to assess the accuracy of the tests. The study began in 2017 and has a target duration of five years. On December 14, 2020, AnPac declared significant progress in detecting pre-cancer diseases with this work and had evaluated over 13,000 individuals in the study. The results demonstrated CDA technology's ability to classify patients into varying levels of cancer risk for more than 20 types of pre-cancer diseases, subsequently confirmed by hospital or physical check-ups. CDA was particularly adept at detecting thyroid nodule/tumor and pulmonary nodule with over 90% confirmed pre-cancer patients that had received a medium to high-risk CDA designation. Out of the group of subjects, CDA screened out pre-cancer cases at a rate 4.5x that of cancer cases, demonstrating CDA's potential in cancer prevention. The study and results are in the process of formal publication.

In an update from the previous study communication, an interim readout on the study was provided, current as of the end of March 2021. Up to the cutoff date, AnPac had contacted 23,857 individuals who had received the screening test. Of this group, 14,127 of the test recipients provided substantive feedback on their health condition and disease development. 1,928 of the respondents had been diagnosed with major diseases by third-party hospitals or medical institutions within two years of taking the CDA test. 209 of the individuals were diagnosed with cancers, 962 with pre-cancers or benign tumors and 757 with major non-cancerous diseases. All of these diagnoses were in the high and medium cancer risk test result groups.

Exhibit I – Interim Study Results

Cancer Risk Test Result	Feedback	Disease Diagnosis	Proportion
High	836	209	25.0%
Medium	11,328	1,719	15.2%
Low	1,963	0	0%
Total Respondents	14,127	1,928	

AnPac's CDA technology leverages the biophysics of blood for screening. The company leverages a number of detection technologies to achieve this end, including novel sensor design, sensor fabrication, detection process, signal collection, signal processing and proprietary algorithms. Identifying pre-cancer diseases serves a valuable role as an early warning for cancer, calling for intervention when it matters most.

Early detection has a dramatic impact on survival. For example, the five-year survival rate for lung cancer is over 50% for cases when the disease is localized in the lungs but only 5% in more advanced stages.[3] There is a broad selection of treatments for cancer; however, they are less effective when the disease has progressed to advanced stages. Early detection and diagnosis are crucial for efficiently and effectively treating this common malignancy. There are many screening tools available but the diagnostics suffer from low levels of accuracy, high costs, inconvenience and discomfort and a need for multiple tests to cover the most common cancer types. Results from evaluating CDA in pre-cancer diseases hold promise as a scalable, and comprehensive screen for early intervention.

AnPac's announcement marked the completion of a prospective larger population screening, using CDA, of over 110,000 individuals and over 150,000 samples. The follow-up tracked the course of patients of varying cancer risk as assessed by CDA.

US Patent Granted

AnPac received approval for patent number 10,895,573, announced February 1, 2021. The patent is entitled "Apparatus for Detecting Tumor Cells" and was granted on January 19, 2021 which describes an apparatus for interacting with a biological subject to detect circulating tumor cells. It is able to send a signal to the biological sample and receive a response to the signal from the biological entity. The patent has 38 claims, covering a range of novel features for multi-cancer detection, including the detection apparatus, components, reagents, mechanisms and detection parameters, including biophysical properties.

New Sensor

AnPac announced in March that they had developed a second generation sensor for cancer detection that exhibits improved signal and yield performance. The new iteration is called the CDA Pro Sensor (CDAPS) and it offers improved detection signal stability, sensor device yield, cost and detection accuracy. Advancements made in design, fabrication and packaging processes are expected to enhance the competitiveness of AnPac's cancer screening.

AnPac is now in the process of transitioning to the new sensor in its CDA machines, first in China then in the United States. Tests using the new component began earlier this year in the Philadelphia lab and will be included in the devices seeking FDA approval.

[3] American Cancer Society, Lung Cancer Survival Rates

Company Milestones

- IPO on NASDAQ – January 2020
- Addition of new insurance customers – February 2020
- San Jose lab CAP Accreditation – March 2020
- Philadelphia lab opening – July 2020
- Philadelphia lab CLIA Lab Certification – August 2020
- New contract with Beijing Yuan Jian Health Management – June 2020
- Filing of various patent applications in the US - 2020
- Regain compliance with NASDAQ listing requirement – March 2021
- 237 patent applications and 142 patents granted to date – March 2021
- Class III Medical Device Registration Certificate – December 2021
- San Jose, CA Lab CLIA and CAP certification.

Key reasons to own AnPac Bio shares:

- **Swiftly growing demand for cancer screening**
- **Rapid, inexpensive screening process for the most common cancers using a single blood sample**
- **High incidence and prevalence of cancer in primary markets of China and US**
- **Effective screening approach using biophysical properties**
    - **Substantial literature supportive of the approach**
    - **Prospective studies presented at ASCO demonstrate high accuracy**
- **Physical labs in place in China and the US**
- **Extensive history of research associating biophysical properties of blood with cancer**
- **Opportunity to expand suite of products to provide additional services**
    - **Therapy selection**
    - **Treatment monitoring**
    - **Genomic testing**
- **Development platform that can be applied to many genetic tests and cellular therapy applications**

Summary

AnPac is approaching diagnostic cancer screening from a new direction that identifies the biophysical properties of blood to identify cancer risk. Not only is this approach uncorrelated and potentially synergistic with other testing approaches that use DNA sequencing but it is also much less costly with simpler detection mechanisms. The company is in an attractive market as there are an estimated 18 million cases of cancer a year, and as the likelihood of the disease increases with age, there is also a demographic tailwind to anticipated demand as the older population is expected to increase at a faster rate than the population overall. Research has shown that catching cancer early can have a dramatic impact on survival and on the total cost of treatment, which can make a strong economic case to employers and health plans who want to keep their people on the job and reduce spending on preventable disease. Current screening approaches are poor and present accuracy levels that create an undue burden on the health care system and on the patients who use them, either through unnecessary worry, cost and procedures for a false positive, or failure to catch the disease for a false negative.

In the past several months since our last update, AnPac publicized further results showing CDA's ability to screen for pre-cancer disease. AnPac was granted a US patent for multi-cancer detection and has upgraded the sensor used to produce CDA values. The company has also received approval from the NMPA to begin registration testing, targeting commercialization in China. Activity has accelerated in the first quarter of 2021 with testing growth of 130% over prior year levels suggesting topline trends in line with our estimates. We maintain our price target of $8.00 per share.

PROJECTED FINANCIALS

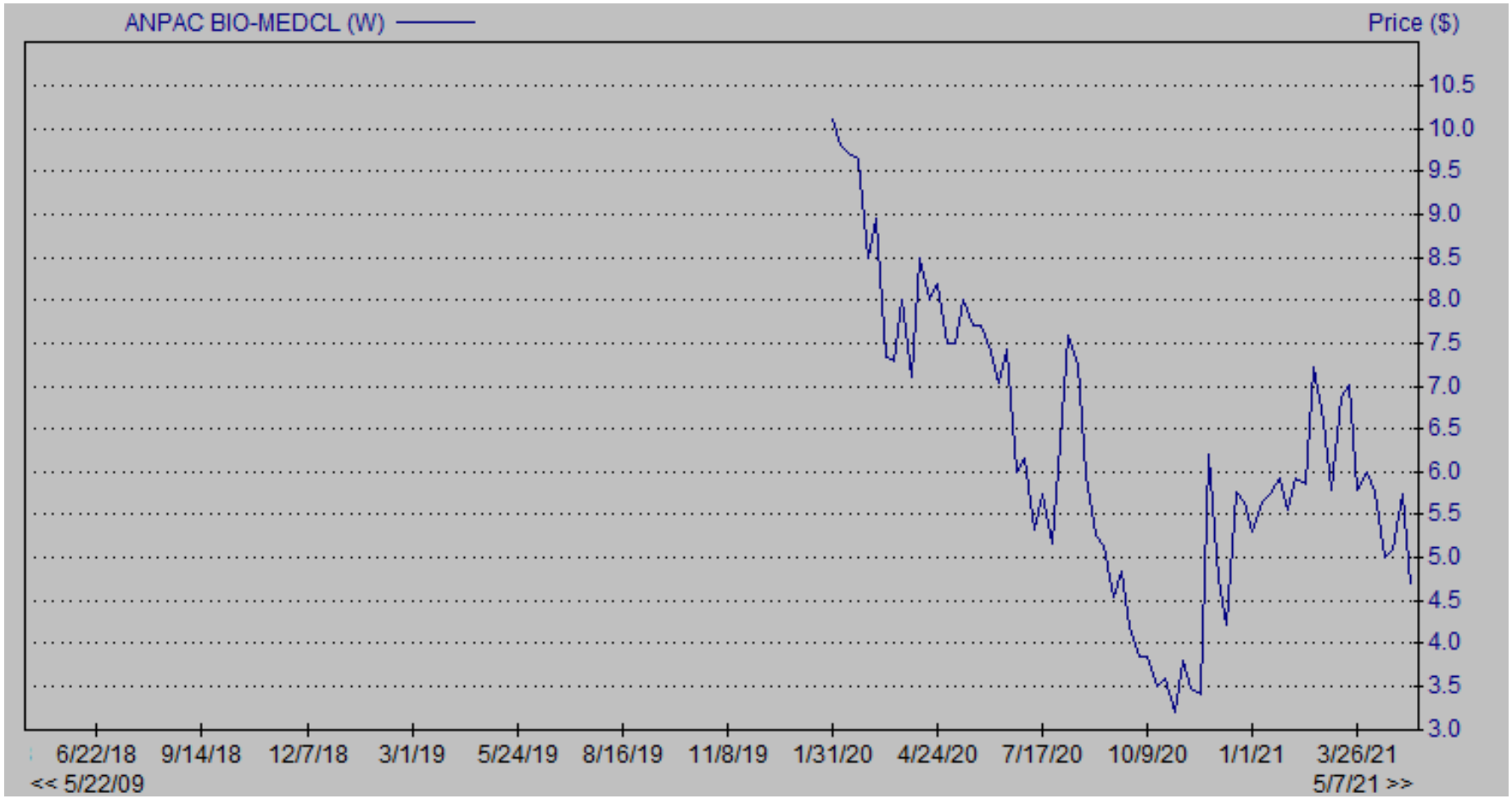
AnPac Bio-Medical Science Co., Ltd. - Income Statement

AnPac Biomedical Science Co.	2019 A	1H A	2H A	2020 A	2021 E	2022 E
Total Revenues ($USD)	**$1,558**	**$573**	**$2,570**	**$3,143**	**$6,461**	**$11,489**
Cost of Goods Sold	$869	$313	$856	$1,169	$2,861	$4,825
Gross Margin	44.2%	45.4%	50.0%	62.8%	55.7%	58.0%
Gross Profit	**$689**	**$260**	**$1,714**	**$1,974**	**$3,599**	**$6,663**
Selling & Marketing	$1,958	$661	$2,354	$3,015	$2,240	$2,417
Research & Development	$1,413	$1,052	$722	$1,774	$1,400	$1,540
General & Administrative	$10,167	$7,175	$4,282	$11,457	$6,460	$6,718
Other Income	($54)	($7)	$226	$219	$0	$0
Operating Income	($12,795)	($8,621)	($5,870)	($14,491)	($6,501)	($4,012)
Operating Margin	*-821.2%*	*-1504.5%*	*-228.4%*	*-461.1%*	*-100.6%*	*-34.9%*
Interest Income (Expense)	($375)	($73)	($102)	($175)	($360)	($360)
Total Other Income	($1,457)	$753	$1,553	$2,306	$0	$0
Pre-Tax Income	($14,546)	($7,938)	($4,436)	($12,346)	($6,820)	($4,347)
Income Tax	$31	$5	$8	$13	$20	$13
Tax Rate	0%	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($14,515)	($7,933)	($4,428)	($12,333)	($6,799)	($4,334)
Reported EPS	**($1.62)**	**($0.72)**	**($0.39)**	**($1.10)**	**($0.44)**	**($0.23)**
YOY Growth	122.2%			*-32.1%*	*-59.7%*	*-48.7%*
Shares Outstanding	8,938	10,952	11,500	11,190	15,300	19,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

AnPac Bio-Medical Science Co., Ltd. – Share Price Chart[4]



[4] Source: Zacks Research System

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